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CONTEMPT PROCEEDINGS AGAINST SECRETARY OF HEW JOSEPH A. CALIFANO, JR.

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OF THE

SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS

OF THE

COMMITTEE ON INTERSTATE AND FOREIGN COMMERCE

HOUSE OF REPRESENTATIVES

NINETY-FIFTH CONGRESS

SECOND SESSION

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CONTEMPT PROCEEDINGS AGAINST SECRETARY OF HEW JOSEPH A. CALIFANO, JR.

WEDNESDAY, AUGUST 16, 1978

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS,
COMMITTEE ON INTERSTATE AND FOREIGN COMMERCE,
Washington, D.C.

The subcommittee met, pursuant to notice, at 9:35 a.m., in room 2322, Rayburn Office Building, Hon. John E. Moss (chairman of the subcommittee) presiding.

Mr. Moss. The committee will come to order.

The subcommittee has a number of important matters to take up this morning. In the course of our usual business we have two reports to consider and some housekeeping items.

Before our usual business, however, we are sidetracked with some extraordinary business, concerning an issue of congressional prerogative I had thought long ago to be well settled.

We are here for the return of subpena No. 95—2–75, duly authorized by this subcommittee on July 27, 1978, and directed to the Honorable Joseph A. Califano, Jr., Secretary of the Department of Health, Education, and Welfare. That subpena, served August 10, 1978, on HEW General Counsel Peter Libassi, calls for the delivery to this subcommittee of certain materials pertinent to one of our more important investigations.

The subcommittee's interest in these materials is substantial. We are engaged in an investigation of the regulation of drugs. Included within the scope of this investigation is a review of allegations that a number of drug companies put their trade names on drugs actually manufactured by generic drug companies.

One way of claiming manufacturing responsibility for a drug is for a trade name company to position an employee in a generic drug house while the product is being manufactured.

The subcommittee is not convinced that this "man-in-the-plant" performs any function which changes the manufacturing process usual for the generic drug house.

In spite of the fact that the man-in-the-plant may be no more than a token representative for the trade name company, prices charged by the trade name company are often much higher than the same drug that is made and sold by the same generic drug manufacturer.

To determine the significance of the man-in-the-plant in terms of difference in product quality, this subcommittee requested documents from HEW and held by the Food and Drug Administration (FDA).

These documents contain information the manufacturers are required to file with the FDA regarding manufacturing processes, control procedures, and testing methods.

The information we seek is also directly relevant to legislation presently before the House. The Drug Regulation Act, H.R. 12980, now before the Subcommittee on Health and the Environment, of the Committee on Interstate and Foreign Commerce, is considering provisions which could limit or eliminate the man-in-the-plant practice.

Other legislative considerations include amendment of the Food, Drug, and Cosmetic Act, also under the jurisdiction of this committee, to insure that true manfacturing responsibility of a product be stated on the label.

Moreover, in exercising this subcommittee's very specific oversight responsibilities, we are concerned that the FDA make full and effective use of the statutory powers it already has. It has been asserted that FDA could and should have promulgated regulations under the present act to disallow the man-in-the-plant practice.

The authority of the subcommittee to carry out this investigation is clear. By a resolution of the Committee on Interstate and Foreign Commerce agreed to on February 8, 1977, this subcommittee was given the "responsibility for oversight of agencies, departments, and all programs within the jurisdiction of the full committee and to conduct such investigations within such jurisdiction." Clause 1(l) of rule X of the Rules of the House of Representatives provides the Committee on Interstate and Foreign Commerce with jurisdiction over, among other matters, "Interstate and foreign commerce generally"; "public health and quarantine"; "health and health facilities, except health care supported by payroll deductions."

With these grants of jurisdiction come responsibilities which the Chair takes very seriously. Rule X provides that:

> Each standing committee—other than the Committee on Appropriations and the Committee on the Budget—shall review and study, on a continuing basis, the application, administration, execution, and effectiveness of those laws, or parts of laws, the subject matter of which is within the jurisdiction of that committee, and the organizations and operation of the Federal agencies and entities having responsibilities in or for the administration and execution thereof, in order to determine whether such laws and the programs thereunder are being implemented and carried out in accordance with the intent of the Congress and whether such programs should be continued, curtailed, or eliminated.
>
> In addition, each such committee shall review and study any conditions or circumstances which may indicate the necessity or desirability of enacting new or additional legislation within the jurisdiction of that committee—whether or not any bill or resolution has been introduced with respect thereto—and shall on a continuing basis undertake future research and forecasting on matters within the jurisdiction of that committee.

Accordingly, the documents we require here are directly pertinent to the subcommittee's current investigation, which is squarely within the authority and jurisdiction of the subcommittee, pursuant to a plainly valid legislative purpose.

Unfortunately, we have run into some trouble obtaining the materials we require. In the past several weeks, the subcommittee has made every reasonable attempt to achieve, without compulsory process, a result consistent with the needs of the subcommittee and the convenience of the Department of Health, Education, and Welfare. To wit:

On July 11, 1978, in a letter hand delivered to Secretary Califano, the subcommittee requested documents relating to the man-in-the-plant manufacture of drugs.

On July 20, 1978, subcommittee staff met with FDA Commissioner Donald Kennedy and his staff. In that meeting, our request for documents was significantly narrowed. For the first time, disclosure of certain documents was questioned by the Commissioner.

On July 21, 1978, in a letter hand delivered to Secretary Califano, the subcommittee again requested documents from the Secretary. This request had been considerably narrowed since the request made on July 11, 1978. This letter has yet to receive a written response.

Since the letter of July 21, the Secretary's staff has repeatedly asked for deadline extensions to allow time for review of our requests. The subcommittee, just as regularly, granted every requested extension.

Finally, and reluctantly, after negotiations had clearly broken down, and it was apparent that HEW had no intention of delivering the required materials in the forseeable future, we served subpena No. 95–2–75. That subpena, with all the force and dignity of Article I of the U.S. Constitution, compels production of these documents.

To answer that subpena this morning—perhaps even to comply with it—we are pleased to welcome the Honorable Joseph A. Califano, Jr., Secretary of Health, Education, and Welfare, and, of course, chief custodian of the materials in question.

I might say, we have enjoyed being Secretary Califano's friend for some time—and on one occasion his employer—and look forward to a long and abiding relationship in the future.

By the way, Mr. Secretary, if I neglected to publicly thank you for the superb job you did in representing this subcommittee in the courts 2 years ago, and helping us to successfully vindicate the constitutional right of Congress to information in the hands of Government agencies, let me resoundingly do so now.

I am aware that HEW has solicited the advice of the Justice Department in this matter, and that in a letter written after HEW's intent not to comply with our request was clear, Acting Attorney General Michael J. Egan apparently concluded that Secretary Califano should not comply.

Mr. Egan apparently relied on an obscure clause in the Federal Food, Drug, and Cosmetic Act which prohibits FDA employees from disclosing information such as that we seek, to third parties for personal gain. Mr. Egan raised by implication the unseemly, but altogether implausible specter of Cabinet Officer A prosecuting Cabinet Officer B.

I am confident that such a dispute within the Cabinet family could and would be handily resolved by a concerned and effective President.

However, that may be, it is not our concern. What is our concern is obtaining the information to which we have a constitutional right.

At this time, Mr. Secretary, would you stand and be sworn?

Do you solemnly swear that the testimony you are about to give this subcommittee is the truth, the whole truth, and nothing but the truth so help you God?

Secretary CALIFANO. I do.

Mr. Moss. And would you care to introduce those who accompany you here today?

Secretary CALIFANO. On my right is Peter Libassi, the General Counsel of the Department of Health, Education, and Welfare.

On my left I have Richard Cooper, Counsel for the Food and Drug Administration.

Mr. Moss. Mr. Secretary, has the subcommittee supplied you with the relevant rules and resolutions of the House of Representatives and the Committee on Intersate and Foreign Commerce?

TESTIMONY OF HON. JOSEPH A. CALIFANO, SECRETARY, DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE, ACCOMPANIED BY PETER LIBASSI, GENERAL COUNSEL, HEW; AND RICHARD M. COOPER, CHIEF COUNSEL, FOOD AND DRUG ADMINISTRATION, HEW

Secretary CALIFANO. Yes; Mr. Chairman.

Mr. Moss. Did you hear my opening statement in which I summarized this subcommittee's authority, legislative interests, and the pertinence of the subpenaed material to its current investigation?

Secretary CALIFANO. Yes; Mr. Chairman.

Mr. Moss. Did you on August 10, 1978 receive a copy of the subcommittee subpena dated August 4, 1978 and numbered 95–2–75?

Secretary CALIFANO. I did, Mr. Chairman.

Mr. Moss. Have you brought with you the materials called for by that subpena No. 95–2–75?

Secretary CALIFANO. Mr. Chairman, I have some of those materials. I can describe them briefly, and I also would like to make a few comments. I shall not do that now but I will describe the material if I may.

I have brought with me a preliminary list containing all the information that we have been able to compile since the few days of receiving the subcommittee's subpena.

Shown on this list we have the brand name manufacturer, the drug involved, and the associated manufacturer who may be manufacturing the drug for the better known company. Inasmuch as work on this list began only this week, it is not complete. I would like to submit that to the subcommittee.

This is the first time that the Department has ever released that information. It is regarded, I am advised by my attorneys, as confidential information, but that is a judgment for the committee to make I realize you are not bound by FDA regulations.

I would like to submit the preliminary list and assure the committee that within 30 days I will have a complete list.

Second, I have instructed the Food and Drug Administration, the Commissioner and Mr. Cooper, to go through the applications and forms which the committee has requested in the subpena; to black out trade secret information relating to the manufacturing process, which is the information that the Attorney General says I may not transmit under section 301(j) of the Food and Drug Act; and to provide for the subcommittee to review a couple of examples of that.

If the subcommittee wishes to continue and do that for all the abbreviated NDA's, the subcommittee has requested we shall do so—but the trade secret information relating to the manufacturing processes, to which the statute applies, will be blacked out.

That, Mr. Chairman, is the information I have brought with me and the information that we shall submit to the subcommittee.

Mr. Moss. The subcommittee, of course, is most appreciative that this material is being supplied. I think you recognize clearly that the action by the Department in deleting the material from the subpenaed information does not comply with the needs of the subcommittee.

Is there any physical or practical reason these materials have not been provided?

Secretary CALIFANO. Mr. Chairman, if I may just briefly—I would like to submit for the record a brief statement and cover just the highlights of it in response to that question in order to explain why we are not submitting the material, if I may.

Mr. Moss. I think if we complete our inquiry here, we can then deal with the matter of further explanation and testimony.

In other words, if you can just give us the answer to the question.

Secretary CALIFANO. The reason I am not submitting the material, Mr. Chairman, is because of an opinion from the Office of the Attorney General, the Acting Attorney General, that that is material which I am prohibited from supplying, and any employee of HEW is prohibited by section 301(j) of the Food and Drug Act from transmitting that material outside the Department except through a court under criminal penalty of a year in prison or a fine of $1,000.

Mr. Moss. Mr. Secretary, is that the opinion prepared by Mr. Egan at the time he was Acting Attorney General?

Secretary CALIFANO. Yes.

Mr. Moss. That opinion, without objection, will be placed in the record at this point.

[The material referred to follows:]

THE UNDER SECRETARY OF HEALTH, EDUCATION, AND WELFARE,
Washington, D.C., August 9, 1978.

Hon. GRIFFIN BELL,
Attorney General, Department of Justice,
Washington, D.C.

DEAR JUDGE BELL: On July 11, the Subcommittee on Oversight and Investigations of the House Committee on Interstate and Foreign Commerce notified the Secretary that it was conducting an investigation into the regulation of drugs and requested access to certain records. On July 21, the Subcommittee requested additional records in connection with their investigation. The scope of the Subcommittee's requests are set forth in the enclosed letters. We understand that the Committee on Interstate and Foreign Commerce may issue a subpoena for those records.

Secretary Califano has disqualified himself from participation in this matter because, while in private practice, he represented the Chairman of the Subcommittee on Oversight and Investigations in litigation involving a similar matter. Responsibility for responding to the Subcommittee's requests and a subpoena, should it be issued, therefore rests with me.

It is my desire to be as cooperative as possible with the Subcommittee, and to provide access to the requested records if possible. However, I am advised by the General Counsel of the Department that some of these records contain information which constitutes a trade secret within the meaning of Section 301(j) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 331(j). I am further advised that I could be subject to criminal sanctions for disclosing such trade secrets in violation of the prohibitions of that section.

Accordingly, would you please advise me whether in the Justice Department's view disclosure of these records to the Subcommittee in response to the enclosed requests or to a subpoena is prohibited by Section 301(j).

Sincerely,

HALE CHAMPION.

Enclosures.

Office of the Attorney General
Washington, D. C. 20530

9 AUG 1978

Honorable Hale Champion
Under Secretary
Department of Health, Education,
and Welfare
Washington, D.C. 20201

My Dear Mr. Under Secretary:

You have asked for my opinion whether the Department of Health, Education, and Welfare (HEW) may lawfully disclose to a congressional committee certain information in the Department's possession acquired from drug manufacturers pursuant to the provisions of the Federal Food Drug and Cosmetic Act, 52 Stat. 1040, as amended, 21 U.S.C.§§ 301 et seq. You state, and we assume for purposes of this opinion, that the House Committee on Interstate and Foreign Commerce has officially demanded information some of which constitutes trade secrets falling within the terms of section 301(j) of the Act, 52 Stat. 1042, as amended, 21 U.S.C. § 331(j).

It is my conclusion that section 301(j) by its terms prohibits you, or any other official of HEW, from disclosing to a congressional committee trade secrets, acquired pursuant to the sections cited therein. The section explicitly provides:

> The following acts and the causing thereof are hereby prohibited:
>
> * * * *
>
> (j) The using by any person to his own advantage, or revealing, other than to the Secretary or officers or employees of the Department, or to the courts when relevant in any judicial proceeding under this Act,

> any information acquired under authority of sections 404, 409, 505, 506, 507, 510, 512, 513, 514, 515, 516, 518, 519, 520, 704, 706, or 708 of this title concerning any method or process which as a trade secret is entitled to protection.

Disclosure of such information in violation of the terms of section 301(j) is a criminal offense. § 303, 52 Stat. 1043, as amended, 21 U.S.C. § 333(a).

Where an agency is barred by statute from disclosing certain information, congressional committees have no right to that information unless there is a clearly expressed congressional intent to exclude committee access from the general restriction on disclosure. This issue is by no means a new one. In 1975 Attorney General Levi, relying on opinions of his predecessors, opined that a House committee's subpoena served on the Secretary of Commerce did not override the confidentiality requirement of section 7(c) of the Export Administration Act of 1969, 83 Stat. 845, 50 U.S.C. App. 2406(c), 43 Op. A.G. No. 4 (1975).*/ Attorney General Levi, in reaching this view stated:

> Somewhat similar issues have been considered by prior Attorneys General. See, e.g., 27 Ops. A.G. 150 (1909) (subpoena of Senate committee for confidential information held by the Commissioner of Corporations); 41 Ops. A.G. 221 (1955) (request

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*/ Section 7(c) reads, in pertinent part, as follows:

> No department . . . or official exercising any functions under this Act shall publish or disclose information obtained hereunder which is deemed confidential . . . , unless the head of such department . . . determines that the withholding thereof is contrary to the national interest.

of Senate committee for confidential information held by the Federal Communications Commission); 42 Ops. A.G. no. 46 (1974) (request of House committee for tax return information). The foregoing opinions have proceeded under the general assumption --which I share--that statutory restrictions upon executive agency disclosure of information are presumptively binding even with respect to requests or demands of congressional committees.

That this assumption accords with general legislative intent is demonstrated by the inclusion, in a number of statutes concerning confidentiality of information, of explicit exceptions for congressional requests. 1/ When, as in § 7(c), such an exception is not provided, it is presumably not intended.

1/ See, e.g., 49 U.S.C. 1504 (information obtained by the Civil Aeronautics Board); 7 U.S.C. 12-1 (Department of Agriculture information on boards of trade). Regarding the background of the latter statute, see Freeman v. Seligson, 405 F.2d 1326, 1340-46 (D.C. Cir., 1968).

See also the Freedom of Information Act, 5 U.S.C. 552(c). Id. at 3. [Emphasis added].

It should be noted that the statute at issue in that opinion was less absolute in its terms than section 301(j), since it permitted disclosure "in the national interest." In contrast, the only exception for disclosure outside HEW of the information covered by section 301(j) is disclosure to the courts when relevant to a judicial proceeding.

The Congress itself has taken a strong position in support of the confidentiality of information acquired by the government and protected by such absolute non-disclosure statutes. For example, section 9(a) of title 13 of the United States Code provides that Commerce Department officials

shall not divulge certain census information to persons outside the Commerce Department. It reads, in pertinent part, as follows:

> (a) Neither the Secretary, nor any other officer or employee of the Department of Commerce or bureau or agency thereof, may, except as provided in section 8 of this title --
>
> > (1) use the information furnished under the provisions of this title for any purpose other than the statistical purposes for which it is supplied; or
> >
> > (2) make any publication whereby the data furnished by any particular establishment or individual under this title can be identified; or
> >
> > (3) permit anyone other than the sworn officers and employees of the Department or bureau or agency thereof to examine the individual reports.

Like the Federal Food, Drug and Cosmetic Act, the census provisions authorize the agency to compel individuals and businesses to disclose highly confidential data. 13 U.S.C. § 6(b). Accordingly, Congress has provided for the protection of census data, 13 U.S.C. § 9, and has made it a criminal offense for those obtaining the information to disclose it outside the Department. 13 U.S.C. § 214.

In St. Regis Paper Co. v. United States, 368 U.S. 208 (1961), the Supreme Court held that while federal agencies could not subpoena or otherwise obtain this confidential information from the Commerce Department itself, they could subpoena, from the submitting businesses, their copies of the reports filed with Census. Congress reacted promptly to this decision by passing "clarifying" legislation --

> * * * to provide specifically that company retained copies of census reports submitted to the Bureau of the Census shall have the same confidential status which is afforded to the original census reports submitted to the Bureau of Census.

Senate Report 2218, 87th Cong., 2nd sess. (1962). The legislation amended section 9(a) to add:

> No department, bureau, agency, officer or employee of the Government, except the Secretary in carrying out the purposes of this title, shall require, for any reason, copies of census reports which have been retained by any such establishment or individual. * * * [As amended by Public Law 87-913].

Thus, Congress made it clear that information compelled from business establishments, and declared under penalty of a criminal statute to be confidential, was not to be disclosed outside the receiving department **/ and that this restriction could not be evaded by subpoenaing copies of the compelled reports in the hands of the submitting business.

The parallel between the Census reports and the drug processing information protected by section 301(j) is striking. Both deal with highly sensitive and confidential matter which business establishments are required to submit to the government. Both are deemed sufficiently sensitive that Congress felt obliged to protect confidentiality not only by prohibiting disclosure but by doing so under pain of criminal sanction. In neither case has Congress seen fit to provide an express exemption for disclosure to congressional committees, as it had in the statutes cited in footnote 1 of Attorney General Levi's opinion, quoted above, or in the provisions of the Privacy Act, 5 U.S.C. § 552a(b)(9). Indeed, it is significant that section 301(j) explicitly provides for disclosure to one of the coordinate branches of government, i.e., the courts, but makes no comparable provision for disclosure to committees of the Congress.

It is my view that section 301(j) by its express terms forbids you to disclose trade secret information obtained under the provisions of the Federal Food, Drug and Cosmetic Act to which it refers, and that this prohibition extends to disclosures to committees of the Congress.

Respectfully,

Michael J. Egan
Acting Attorney General

**/ See also, United States v. Little, 321 F. Supp. 388 (D. Del. 1971), reaffirming the absolute confidentiality of census information.

Mr. Moss. We shall also place in the record at this point the opinion which the Chair has obtained from the Library of Congress, the American Law Division.

[The opinion referred to follows:]

THE LIBRARY OF CONGRESS,
CONGRESSIONAL RESEARCH SERVICE,
Washington, D.C., August 7, 1978.

To: Honorable John Moss, Chairman, Subcommittee on Oversight and Investigations, House Committee on Interstate and Foreign Commerce.
From: American Law Division.
Subject: Applicability of Confidentiality Provision to Congress.

This is in response to your inquiry whether the Secretary of H.E.W. or officers of the Food and Drug Administration (FDA) may withhold trade secret information obtained during the course of their statutory activities under the authority of 21 U.S.C. 331(j)(1976), a confidentiality provision which prohibits "The using by any person to his own advantage, or revealing, other than to the Secretary or officers or employees of the Department, or to the courts when relevant in any judicial proceeding under this chapter, any information acquired under authority of sections 334, 348, 355, 356, 357, 360, 360b, 360c, 360d, 360f, 360h, 360i, 360j, 374, 376, or 379 of this title concerning any method or process which as a trade secret is entitled to protection."

Since the provision in issue does not explicitly prohibit or limit congressional access to information collected under the Department's authority, it must be argued that Congress implicitly waived its oversight and investigatory powers[1] with respect to the information now being sought.

Stated differently, the Department's position must be that the statutory restrictions upon disclosure of section 331(j) is presumptively binding even with respect to requests or demands of congressional committees.

This position has been severely criticized in the past[2] and would seem to be unwarranted in the face of the firmly established constitutionally based power of Congress to obtain information pursuant to its investigative and legislative functions. Moreover, the express language, together with the legislative history and context of the provision in question and past congressional practice with regard to confidentiality statutes, leaves little doubt that the Congress did not intend to divest itself of its ability to gather information in this area in this instance.

I

The instant situation raises anew the question as to the scope of Congress' power to carry out its constitutional functions.

Although there is no express provision of the Constitution which specifically authorizes the Congress to conduct investigations and take testimony for the purpose of performing its legislative functions, the practice of the British Parliament and numerous decisions of the Supreme Court of the United States have firmly established that the investigatory power of Congress is so essential to the legislative function as to be implied from the general vesting of legislative power in Congress. *McGrain* v. *Daugherty*, 273 U.S. 135 (1927); *Watkins* v. *United States*, 354 U.S. 178 (1957); *Barenblatt* v. *United States*, 360 U.S. 109 (1959); *Eastland* v. *United States Servicemen's Fund*, 421 U.S. 491 (1975); *Nixon* v. *Administrator of General Services*, 433 U.S. 425 (1977); see also, *United States* v. *A.T.T.*, 551 F. 2d 384 (D.C. Cir. 1976) and 567 F. 2d 1212 (D.C. Cir. 1977). Chief Justice Warren speaking for the Court in *Watkins* described the power as follows:

> We start with several basic premises on which there is general agreement. The power of the Congress to conduct investigations is inherent in the legislative process. That power is broad. It encompasse inquiries concern-

[1] See, 2 U.S.C. 190d (1976).

[2] In 1975, Secretary of Commerce Morton resisted a congressional subpoena for information, citing the general confidentiality provision contained in the Export Administration Act of 1969, 50 U.S.C. App. 2406(c) (amended in 1977). The Attorney General's argument that general confidentiality statutes apply to restrict congressional access was criticized by legal scholars and Secretary Morton, faced with a contempt citation, ultimately furnished the information. See, Contempt Proceedings Against Secretary of Commerce, Rogers C. B. Morton Before the Subcomm. on Oversight and Investigations of the House Comm. on Interstate and Foreign Commerce, 94th Cong., 1st sess. (1975). (Hereafter, Contempt Proceedings).

> ing the administration of existing laws as well as proposed or possible needed statutes. It includes surveys of defects in our social, economic or political system for the purpose of enabling the Congress to remedy them. It comprehends probes into departments of the Federal Government to expose corruption, inefficiency or waste. But, broad as is this power of inquiry, it is not unlimited. There is no general authority to expose the private affairs of individuals without justification in terms of the functions of the Congress . . . Nor is the Congress a law enforcement or trial agency. These are functions of the executive and judicial departments of government. No inquiry is an end in itself; it must be related to, and in furtherance of, a legitimate task of the Congress. 354 U.S. at 187.

Legitimate legislative tasks have been defined as activities that are "an integral part of the deliberative and communicative processes by which Members participate in committee and house proceedings with respect to the consideration and passage or rejection of proposed legislation or with respect to other matters which the Constitution places within the jurisdiction of either House." *Gravel* v. *United States*, 408 U.S. 606, 625 (1972). See also, *Doe* v. *McMillan*, 412 U.S. 306, 313 (1973).

In the *Eastland* case the Court reiterated its view that the power of effective congressional inquiry is an integral part of the legislative process:

> The power to investigate and to do so through compulsory process plainly falls within . . . [the *Gravel* definition of legitimate legislative tasks]. This Court has often noted that the power to investigate is inherent in the power to make laws because '[a] legislative body cannot legislate wisely or effectively in the absence of information respecting the conditions which the legislation is intended to affect or change.' *McGrain* v. *Daugherty*, 273 U.S. 125 175 (1927) . . . Issuance of subpoenas such as the one in question here has long been held to be a legitimate use by Congress of its power to investigate . . .
>
> > '[W]here the legislative body does not itself possess the requisite information—which not infrequently is true—recourse must be had to others who do posses it. Experience has taught that mere requests for such information often are unavailing, and also that information which is volunteered is not always accurate or complete, as some means of compulsion are essential to obtain what is needed.' *McGrain* v. *Daugherty*, supra, 273 U.S. at 175.
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> It has also been held that the subpoena power may be exercised by a committee acting, as here, be half of one House . . . Without such power the Subcommittee may not be able to do the task assigned to it by Congress, *Eastland* v. *U.S. Servicemen's Fund*, 421 U.S. at 504–505.

Thus it is quite clear that your Subcommittee's broad oversight mandate, which includes the particular Department and matters now the subject of investigation and possible legislative action, entitles it to exercise plenary investigative and information gathering authority unless some other statutory restriction or constitutional privilege may be raised to limit that power.

Careful examination of 21 U.S.C. 331(j) reveals that neither its express language nor any necessary implication from that language restricts access by duly authorized committees of Congress to information held by the Department of H.E.W. Indeed, it would be highly unusual for Congress to limit or divert itelf of its constitutional and statutorily mandated oversight functions[3] by indirection. To the contrary, in the past Congress has shown that it is fully capable of limiting is access to information from the Executive to certain committees or, in rare instances, to the Congress as a whole, in a clear and explicit manner.

For example. § 1 of Pub. L. 92–403, 1 U.S.C. 112b, limits congressional access to international agreements, other than treaties, where, in the opinion of the President, public disclosure would be prejudical to the national security of the United States. In that event such agreements "shall not be so transmitted to the Congress but shall be transmitted to the Committee on Foreign Relations of the Senate and the Committee on Foreign Affairs of the House of Representatives under an appropriate injunction of secrecy to be removed only upon due notice from the President."

Similarly, the Internal Revenue Code limits inspection of tax returns to the Senate Finance Committee, House Ways and Means Committee, and the Joint Committee on Internal Revenue Taxation or any select committee "specifically authorized to investigate returns by a resolution of the Senate or House." 26

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[3] See 2 U.S.C. 190d (1976).

U.S.C. 6103(d), 6104(a)(2). In a statute requiring reporting to Congress on certain sensitive positions created in the Defense Department, "the Secretary may omit any item if he considers a full public report on it would be detrimental to the national security."

But he must present the information in executive session to such committees of either House as may be designated by the presiding officers of those bodies. 10 U.S.C. 1582. Also, until recently, the Atomic Energy Act contained an express provision respecting access to "restricted data" and created a Joint Committee on Atomic Energy that exclusively receives information from the various agencies with respect to the activities and responsibilities of such agencies in the field of atomic energy. See 42 U.S.C. 2161–2166, 2251–2257, 2277 (1970).

Finally, several provisions of the United States Code expressly limit certain types of information available to Congress generally. For example, under 50 U.S.C. 402g, j(b), the Congress' ability to obtain information about the Central Intelligence Agency, particularly with regard to expenditures, is severely limited.

On the other hand, if the Secretary's construction of the provision is accepted, it would mean that over 100 similar confidentiality provisions[4] could also be invoked by executive agencies against congressional requests for information. The effect of such a construction would be to vitiate a substantial portion of Congress' oversight jurisdiction by implication, an incongruous consequence not obviously intended by Congress. Cf., *FAA Administrator* v. *Robertson*, 422 U.S. 255 (1975) where the Court rejected an interpretation of Exemption 3 of the Freedom of Information Act which would have had the effect of impliedly repealing over 100 confidentiality statutes. The Court emphasized that there must be a clearly expressed intention for a statute to have such a drastic effect.

It is difficult to accept such a construction on the face of the provision. Section 331(j) prescribes two types of activities. First, no one may use a trade secret lawfully obtained under the Act for his own advantage. Second, no one may reveal trade secrets as obtained except to the Secretary or officers or employees of the Department or to the courts in a proper proceeding. It would appear, then, that the Secretary and other officers of the agency are not prohibited by this provision from revealing such information if it is not to their "own advantage."[5]

Thus the limitation on disclosure, it may be plausibly argued, is aimed at the first level collectors of the information, a construction which is confirmed by the legislative history of the provision. In any event, of overriding significance for present purposes is the fact that neither the express language of the provision nor any necessary implication from those words indicates a congressional intention to be precluded from receiving the covered information, even if the provision is read to preclude official disclosure anywhere else.

In this regard it may be noted that in 1976 Congress amended the Act to provide that the Secretary could reveal trade secrets to contractors with the Department if appropriate security is ensured and if it is necessary to further the purposes of the Act. See Pub. L. 94–295, sec. 8, 21 U.S.C. 379 (1976). Thus the prohibition against disclosure is confirmed not to be overly broad, and that at least some discretion is vested in the Secretary by section 331(j)[6] is apparent. In light of this, it would seem peculiar that Congress would allow disclosure of trade secrets to private parties, yet totally deprive itself of any opportunity to see that information.

III

The legislative history of the subject provision demonstrates that the restrictive construction placed on it by H.E.W. is contrary to its intended purpose. Efforts to amend the Federal Food and Drugs Act of 1906 commenced in earnest with the introduction in the 73rd Congress by Senator Copeland of S. 1944 in June 1933. Opposition resulted in the bill being twice revised, first as S. 2000 and later as S. 2800. It was in S. 2000 that the initial version of section 331(j) appeared as section 17(g):

> (g) Any person who uses to his own advantage or reveals, other than to the Secretary or his officers or employees, or to the courts when relevant

[4] For this compilation of statutory provisions see Contempt Proceedings, Appendix T, pp. 210–254.

[5] Disclosure of such information may be prohibited by *other* statutes, such as 18 U.S.C. 1905. But, as is indicated below, even that general prohibition does not apply to disclosures to the Congress.

[6] Senate Report No. 94–33 at p. 33 makes it plain that the provision was meant to amend section 331(j).

in the trial of any case under this Act, any information acquired under authority of sections 12 or 13 concerning any method or process which is entitled to protection in equity as a trade secret, shall be guilty of a felony, and shall on conviction thereof be subject to imprisonment for not more than two years or a fine of not more than $5,000 or both such imprisonment and fine.

The provision was repeated in S. 2800 and that proposal became the focal point for consideration in that Congress. Senate Report No. 493, 73d Cong., 2d Sess. (1934), accompanying S. 2800 explains that the confidentiality provision was meant to be complementary to sections 12 and 13 of the bill. Those sections gave authority to the Secretary to make plant inspections and implemented that authority by means of court injunctions and contempt proceedings. The purpose of section 17(g) was to allay the fears of manufactures that the inspectors who entered their premises under that authority utilize that opportunity to purloin valuable trade secrets. The report states:

"Section 13. Factory Inspections

"The existing law imposes upon the Secretary of Agriculture and enforcement officials acting under him the duty of locating and reporting shipments of adulterated and misbranded food and drugs in interstate commerce but fails to confer upon them the right to enter upon the premises of manufacturers and dealers where such food and drugs are being manufactured or held in storage for the purpose of ascertaining the necessary facts for the proper performance of the duties thus imposed. Section 13, paragraph (a), of the bill would confer such authority upon officers and employees designated by the Secretary of Agriculture. Authority to inspect premises is usually regarded as an indispensable implement for the enforcement of statutes enacted for the protection of the public health. This assertion is borne out by the fact that State laws and municipal ordinances, generally, confer such authority upon local health, food, and drug officials and in some instances go so far as to authorize the summary destruction of food or drugs by such officials without affording a right of review, whenever such food and drugs are inimical to public health. Paragraph (a) cannot therefore, be regarded either as an unreasonable grant of authority or as a new departure in the annals of American legislation.

In order to reinforce paragraph (a), paragraph (b) would confer jurisdiction upon the District Courts of the United States to enjoin manufacturers and shippers of food, drugs, or cosmetics from using the channels of interstate commerce if they should refuse to permit reasonable inspection by the Federal officials even though it is not authorized by the existing law. The persistent refusal of a small minority makes a measure of compulsion necessary, even though, once it is provided, the occasions for its use will probably be rare. Paragraph (g) of section 17 is complementary to sections 12 and 13, and should be read in connection with each. It provides a safeguard to the property rights of manufacturers, by making the unauthorized use or disclosure of any information obtained under authority of sections 12 or 13 concerning any method or process which is entitled to protection in equity as a trade secret, a felony punishable by fine or imprisonment, or both.

* * * * * * *

"Section 17. Penalties

* * * * * * *

"As a safeguard to manufacturers, paragraph (g) would penalize the improper use or disclosure of any information *obtained by Government inspectors* under authority of sections 12 or 13 concerning any secret method or process in use in any plant."

Thus it would appear that the prohibition was primarily aimed at the activities of field inspectors. There is no evidence in the report, the floor debates or hearings in 73rd Congress, or in the reports, debates or hearings in any subsequent Congress in which the legislation was considered, that the confidentiality provision in question was ever meant to run against the Congress.

Senator Copeland reintroduced his measure in the 1st session of the 74th Congress as S.5 with the confidentiality provision, now placed at section 708(a)(9), reading as follows:

(9) The using by any person to his own advantage, or revealing, other than to the Secretary or his officers or employees or to the courts when rele-

vant in the trial of any case under this Act, any information acquired under authority of sections 305 or 707 concerning any method or process which as a trade secret is entitled to protection.

Senate Report No. 361, 74th Cong., 1st Sess. (1035), pp. 26–28, essentially makes the same explanation of the complementary nature of the plant inspection and disclosure provisions:

SECTION 707. FACTORY INSPECTION

Paragraph (a) of section 707 authorizes inspectors of the Department, after making reasonable request and obtaining permission of the owner, to enter and inspect establishments manufacturing goods for interstate commerce or holding such goods after receipt in interstate commerce. It also authorizes the inspection of vehicles in which goods are being transported in interstate commerce.

Paragraph (b) of this section imposes the penalty of a small fine for the interstate shipment of goods or their delivery thereafter from establishments or vehicles where permission to inspect has been denied. Liability for such shipments terminates when permission is granted to make inspection.

Authority for such inspections is an indispensable implement for the enforcement at any statute intended ot protect public health. Many of the provisions of this bill, particularly those dealing with filth and insanitary conditions, could not be otherwise effectively applied.

While one of the great weaknesses of the present Food and Drugs Act is the absence of any provision of this kind, it has been found that most manufacturers welcome inspection by Federal officials. Experience has shown that the relatively small minority who refuse permission for inspection in almost every instance are undertaking to hide some reprehensible condition.

Paragraphs (a) (9) and (g) of section 708 are complementary to this section and to section 305, and should be read in connection with each. They safeguard the property rights of the manufacturer by making the unauthorized use or disclosure of any trade secret obtained under authority of these sections a felony punishable by fine or imprisonment or both.

SECTION 708. PROHIBITED ACTS AND PENALTIES

The penalties provided under the present Food and Drugs Act have proved wholly inadequate to bring about substantial compliance with the law on the part of those manufacturers who regard on occasional small fine as an inexpensive license to carry on their illicit operations. The bill would provide for increased fines and for possible jail sentences for first offenses. The courts may, of course, be relied upon to adjust the penalties to the degree of seriousness of the respective offenses.

Under the existing law the willful violator stands on the same plane with the person who inadvertently violates the law through the negligence of his employees. Paragraph (c) will place willful violators in a special category subject to heavier penalties than those who violate the law inadvertently.

Publishers, radio broadcast licensees, and other media for the dissemination of advertising are not in many instances in a position to know the nature of the goods they advertise nor can they be expected to maintain the necessary laboratory equipment and staff of technicians to determine the facts. Accordingly, paragraph (c) will exempt such persons from liability under the law and place the responsibility where it rightly belongs, on the manufacturer or dealer of the advertised product who is in a position to know, and should know, whether the representations concerning his goods are true or false. However, if a publisher or other advertising medium should willfully refuse to furnish the name and post-office address of an advertiser, he would be held guilty of a misdemeanor and subject to penalty.

The existing law provides for a guaranty whereby a dealer who buys on faith may be protected from liability under the law. This provision has safeguarded innocent dealers and has been extremely useful in fixing responsibility on guilty shippers. It would be continued in effect by paragraph (e). The bill affords in this paragraph further protection to the innocent dealer who distributes goods he has received from interstate sources. If he has failed to secure a guarantee he can escape penalties by furnishing the records of interstate shipment, thus allowing the prosecution to lie solely against the guilty shipper. Provision is also made in this paragraph to protect the dealer who disseminates advertising guaranteed to him by the manufacturer.

Retail dealers who sell only at their own establishments frequently advertise articles of local manufacture in small newspapers which are delivered through the mails or which may to some extent be carried across State lines. Since such advertisements are primarily local and not interstate, exemption from prosecution has been extended to retail dealers for such advertising which would otherwise be subject to Federal jurisdiction.

Section 305 contemplates the possible use of stamps, tags, or other identification devices on goods manufactured in plants operating under permit, in order to aid enforcement officials in inspecting such articles found in the channels of interstate commerce. Paragraph (f) provides penalties for the forging, counterfeiting, or simulating of such identification devices. This provision is similar to one contained in the sea-food amendment to the present law. It is not intended that the manufacturer operating under permit should be authorized to use these identification devices for advertising purposes.

As a safeguard to manufacturers, paragraph (g) provides penalties for improper use or disclosure of any information obtained by Government inspectors under authority of sections 305 or 707 concerning any secret method or process in use in any plant.

No other reports in the 74th Congress make further comments on the provision. See Senate Report No. 646, 74th Cong., 1st Sess. (1935); H. Rept. No. 2755, 74th Cong., 2d Sess. (1936).

In the 75th Congress Senator Copeland reintroduced his measure in somewhat revised form and it was again denominated S. 5. As reported to the floor, the confidentiality provision appears at section 3(j) as follows:

> [10] (j) The using by any person to his own advantage, or revealing, other than to the Secretary or officers or employees of the Department, or to the courts when relevant in any judicial proceeding under this Act, any information acquired under authority of section 13 or 27 concerning any method or process which as a trade secret is entitled to protection.

Neither the Senate or House Reports make any comments at all on the provision. Sen. Report No. 91, 75th Cong., 1st Sess. (1937); House Report No. 2139, 75th Cong., 3d Sess. (1938). As indicated previously, neither the floor debates or hearings held on the bill make any substantive comment on the provision, and none, of course, to support the Department's position.[7] The final version of the provision appears at section 301(j) of Public Law No. 715:

PROHIBITED ACTS

> Sec. 301. The following acts and the causing thereof are hereby prohibited:
> (j) The using by any person to his own advantage, or revealing, other than to the Secretary or officers or employees of the Department, or to the courts when relevant in any judicial proceeding under this Act, any information acquired under authority of section 404, 505, or 704 concerning any method or process which as a trade secret is entitled to protection.

IV

Although not specifically raised by the Secretary, Executive agencies in the past have raised several statutes of general applicability as barriers to the disclosure of information to Congressional Committees. None would appear available to H.E.W. under the present circumstances.

The Freedom of Information Act, 5 U.S.C. 552, contains exemptions relating to public disclosure of information "specifically exempted from disclosure by statute" (5 U.S.C. 552(b)(3)) and "commercial and financial information obtained from a person and privileged or confidential" (5 U.S.C. 552(b)(4)). Assuming these exemptions are applicable here, they only apply to disclosure to the public, not to the Congress. 5 U.S.C. 552(c) explicitly states that nothing in the Freedom of Information Act grants the Executive the authority to withhold information from the Congress.

Several criminal statutes have been argued to justify non-disclosure. The one most frequently raised is 18 U.S.C. 1905 which generally proscribes the disclosure of confidential information by a federal officer or employee. That statute provides:

§ 1905. Disclosure of confidential information generally

Whenever, being an officer or employee of the United States or of any department or agency thereof, publishes, divulges, discloses, or makes known in any

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[7] The entire legislative history of the Act is compiled in C. W. Dunn, Federal Food, Drug and Cosmetic Act—A Statement of the Legislative Record (1938).

manner or to any extent not authorized by law any information coming to him in the course of his employment or official duties or by reason of any examination or investigation made by, or return, report or record made to or filed with, such department or agency or officer or employee thereof, which information concerns or relates to the trade secrets, processes, operations, style of work, or apparatus, or to the identity, confidential statistical data, amount or source of any income, profits, losses, or expenditures of any person, firm, partnership, corporation, or association; or permits any income return or copy thereof or any book containing any abstract or particulars thereof to be seen or examined by any person except as provided by law; shall be fined not more than $1,000, or imprisoned not more than one year, or both; and shall be removed from office or employment.

June 25, 1948, c. 645, 62 Stat. 791.

However, this prohibition against disclosure may not be invoked against a request of a standing committee of Congress or one of its subcommittees since it is inapplicable where disclosure is "authorized by law." See, e.g., *Consumers Union* v. *Cost of Living Council*, 491 F. 2d 1396, 1403–1404 (T.E.C.A. 1974); *Grumman Aircraft Engineering Corp.* v. *Renegotiation Board*, 425 F. 2d 578 (D.C. Cir. 1970); *Frankel* v. *S.E.C.*, 376 F. Supp. 675 (S.D.N.Y. 1971), rev'd on other grounds, 460 F. 2d 813 (2d Cir.), cert, denied 409 U.S. 889 (1972); *California* v. *Richardson*, 351 F. Supp. 733 (N.D. Calif. 1972); *M.A. Shapiro and Co.* v. *S.E.C.*, 339 F. Supp. 469 (D.D.C. 1972); *Consumers Union* v. *Veterans Administration*, 301 F. Supp. 796 (S.D.N.Y. 1969); 41 Op. Atty. Gen. 166 (1953); 41 Op. Atty. Gen. 221 (1955); 31 Op. Atty. Gen. 541 (1919).

The above-cited 1955 Attorney General opinion is particularly pertinent to the present situation. That opinion was generated by a request for confidential information from the Senate Committee on Interstate and Foreign Commerce to the Federal Communications Commission. Under the Communications Act the Commission may keep certain specified information confidential. 47 U.S.C. 154j, 213(f), 412. The Commission questioned its authority to furnish the information in light of the provisions of 18 U.S.C. 1905.

The Attorney General held that the authorization required by 18 U.S.C. 1905 was "reasonably implied" under either § 134(a) or 136 of the Legislative Reorganization Act of 1946, 2 U.S.C. 190b, 190d. Under § 134(a) standing committees have the authority to conduct investigations into matters under their jurisdiction and to require the production of such records as they deem advisable. Section 136 imposes on standing committees the duty of exercising "continuous watchfulness" concerning the execution by executive agencies of laws relative to subjects within the jurisdiction of the committees for the purpose of assisting "the Congress in appraising the administration of the laws and in developing such amendments or related information as it may deem necessary." The purpose of this section is to require that the appropriate committees find out and then inform the Congress whether the executive agencies are carrying out the laws entrusted to their execution in accordance with the intent of Congress. Senate Report 1409, 79th Cong., 2d Sess., page 6.[8] The Attorney General concluded as follows (41 O.A.G. at 228):

> These provisions do not expressly authorize disclosure of the type of information referred to in 18 U.S.C. 1905. However, it is sufficient that the authorization is reasonably implied rather than express. 41 Op. A.G. 166. The authority which the Committee has under section 134(a) to require the information in question constitutes in effect an authorization to this section. To the extent that the information is sought by the Committee in the exercise of its duty under section 136, authorization to furnish the requested information to assist in carrying out the purpose of the section is

[8] The 1946 Act only applied to Senate standing committees. The 1970 amendments, however, made § 136 applicable to house standing committees, Pub. L. 92–136, § 1, 2 U.S.C. 190d (1976) and now provides:

> § 190d. Legislative review by standing committee of the Senate and the House of Representatives.
>
> (a) Scope of assistance. In order to assist the Congress in—
> (1) its analysis, appraisal, and evaluation of the application, administration, and execution of the laws enacted by the Congress, and
> (2) its formulation, consideration, and enactment of such modifications of or changes in those laws, and of such additional legislation, as may be necessary or appropriate.
>
> each standing committee of the Senate and the House of Representatives shall review and study on a continuing basis, the application, administration, and execution, of those laws, or parts of laws, the subject matter of which is within the jurisdiction of that committee.

implicit in that cooperation between the Federal agencies and the congressional committees which the Congress intended.

Thus, H.E.W. officials and employees should have no real fear of prosecution under 18 U.S.C. 1905 since the release of the subject information is authorized by law.

CONCLUSION

It is concluded, then, that 21 U.S.C. 331(j) does not prohibit, either by express language or clear implication, disclosure of the matters covered by the statute to an appropriate committee of the Congress. Rather, the language of the legislation and its legislative history, as well as the past practice of Congress with regard to confidentiality statutes, points positively in the direction of Congress retaining unimpaired its plenary oversight authority. Also, neither the Freedom of Information Act nor the prohibition against disclosure of confidential information in 18 U.S.C. 1905 can be raised as an objection to the disclosure of the subject information.[9]

MORTON ROSENBERG,
Legislative Attorney.

Mr. Moss. Mr. Secretary, I have read the Egan opinion. If he were my own attorney, I would dismiss him promptly upon receiving anything as badly prepared as the opinion just referred to by the Secretary.

Are you refusing to comply with the subpena No. 95–2–75?

Secretary CALIFANO. Mr. Chairman, I am refusing to comply with that portion of it which I indicated the Attorney General feels we are prohibited from supplying by law. I would like an opportunity to explain our position.

Mr. Moss. Upon what section of law or the Constitution do you rely in refusing to comply with the subcommittee subpena?

Secretary CALIFANO. Mr. Chairman, can I take about 5 minutes and explain our position generally and our position with respect to this section?

Mr. Moss. As soon as we establish what your purpose is here today, we shall consider a further opportunity to respond.

Secretary CALIFANO. Mr. Chairman, I am not providing that material because of the provisions of section 301(j) of the Food and Drug Act.

There is no question of separation of powers here. There is no question of executive privilege. Congress has the power to change that statute, but the statute, as it is now drafted and as it is now interpreted by the Attorney General, prohibits the transmittal of trade secret information involving manufacturing processes to any person other than to the Secretary, or offices or employees of the Department, or to the courts when relevant in any judicial proceeding under this act.

Congress drafted that statute and Congress can change that statute.

Mr. Moss. Is that the only excuse or defense you have?

Secretary CALIFANO. That is the provision of law, Mr. Chairman,

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[9] In the aftermath of the Morton controversy, Congress amended the confidentiality provision of the Export Administration Act to make explicit the availability of information to Congress, 91 Stat. 235, 241 (1977). The House report on the bill stated:

"The committee finds it incomprehensible that Congress intended by section 7(c) to deny itself access to such information as it might later deem necessary for the effective exercise of its legislative and oversight responsibilities * * *.

"This amendment should not be necessary. It is made necessary only by the decision of the executive branch to interpret section 7(c) in a manner inconsistent with the intent of Congress. The committee presumes that the rights of Congress reaffirmed by this amendment already exists and would exist without this amendment. The addition of this language to this statute is not meant to imply that the absence of similar language in oher statutes in any way limits the right of Congress to acquire information."

H. Rept. No. 95–190, 95th Cong., 1st sess. 17 (1977).

under which we are not providing trade secret information relating to the manufacturing processes.

Mr. Moss. It is the opinion of the Chair that you are without legal justification in your refusal to comply with the subcommittee's subpena.

I again say to you that the subcommittee is authorized to carry out this investigation. The documents subpenaed are pertinent to this investigation, and this investigation is being carried out for a valid legislative purpose.

I now order and direct you to provide the subpenaed material to the subcommittee.

Secretary CALIFANO. Mr. Chairman, I now request an opportunity to explain in detail why I am not providing that material, if I may, and our position in this matter.

Mr. Moss. I would prefer at this point to have a response to the question.

Do you still refuse to supply the subcommittee the subpenaed material?

Secretary CALIFANO. We cannot provide under the opinion of the Attorney General the material which section 301(j) covers, which is trade secret material relating to manufacturing processes. We can provide all the other material which the subcommittee has requested, and I have instructed the Department to provide all of those materials to the subcommittee.

Mr. Moss. Mr. Secretary, you are in the position of the Attorney General being an attorney advising you as a client in the executive department. You are in the Department of Health, Education, and Welfare and the final determining authority after receiving the best advice as to what you will or will not do; is that correct?

Secretary CALIFANO. Mr. Chairman, I think the Attorney General is in a somewhat different position from a lawyer in an ordinary situation. The Attorney General's function is to interpret the law in a manner that he thinks is correct, not in a manner that he thinks advocates one position or another.

His is not like the usual client relationship. Therefore, I do not think he is simply an adviser to me as to what the law says. I believe that I am bound to follow the opinion of the Attorney General.

Mr. Moss. Mr. Secretary, do you understand that the consequence of your refusal may be referred to the Committee on Interstate and Foreign Commerce and to the House of Representatives for appropriate action, action which could lead to criminal penalties toward you?

Secretary CALIFANO. It is because I understand that that I request an opportunity to briefly explain in detail our position on this matter.

Mr. Moss. You still refuse to supply the subpenaed materials to the subcommittee?

Secretary CALIFANO. I think in fairness I should be given that opportunity.

May I explain our position in some detail, Mr. Chairman?

Mr. Moss. Mr. Secretary, I have on two previous occasions been asked to deal with a similar matter. We are according you every bit of fairness that we can, and fairness consistent with the previous actions of this subcommittee in similar cases.

The fact is that you do refuse to supply the material to the committee, that you have supplied us with a copy of the opinion of the Attorney General, that we have read the opinion, and we are acting upon expert advice also and have concluded that there is no valid basis for the Secretary not to comply with the demands of this subcommittee.

Secretary CALIFANO. Mr. Chairman, I request an opportunity both to submit for the record a statement explaining the position of the Department in this matter and also an opportunity to cover a substantial portion of that statement.

The CHAIR has just informed me that there is the possibility of my being held in contempt. I think most rudimentary rules of fairness would give me an opportunity to explain our position in this matter.

I would respectively ask for that opportunity.

Mr. LENT. If I may interrupt for a moment, I would like to state that my own personal view is that rudimentary due process which this committee has been concerned with in the past several months in connection with another investigation would certainly mitigate in favor of giving the Secretary an opportunity to make a statement as to the reasons he is not producing these documents.

I think if we deny him that right at this time we might, in effect, be undermining the validity of any contempt proceedings which might subsequently take place.

Mr. MOSS. Without objection, the Chair will permit the placing in the record at this point of a statement fully setting forth the position of the Department of Health, Education, and Welfare on the matter of the subpena.

[Secretary Califano's statement and attachments follows:]

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

TESTIMONY OF

SECRETARY JOSEPH A. CALIFANO, JR.

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

BEFORE THE

SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS

OF THE

HOUSE COMMITTEE ON INTERSTATE AND FOREIGN COMMERCE

August 16, 1978

Mr. Chairman and members of the Subcommittee:

I am pleased to appear before this distinguished Subcommittee to discuss the response of the Department of Health, Education, and Welfare to a subpoena of August 4, 1978, requesting that I produce copies of "all Abbreviated New Drug Applications" and supporting forms and attachments filed by thirteen drug companies since January, 1965.

These documents are being sought because, as you stated yesterday, Mr. Chairman: "We have long suspected that a number of trade-name drug companies put their trade names on drugs actually manufactured by generic drug companies, resulting in higher consumer prices for the same exact drugs. HEW has the documents which might settle that question, and we intend to get them."

Mr. Chairman, it is important that we keep three points clearly in view.

First, the Commissioner of the Food and Drug Administration and I are deeply committed both to promoting the use of less expensive generic drugs and to ending the drug

companies' practice of secretly marketing generic drugs produced by other manufacturers as their own, more expensive brand name products. We have taken actions to achieve both these goals.

Second, I have directed the Department to produce all the information that we can short of violating a criminal statute passed by the Congress. Indeed, I am today, pursuant to the subpoena, providing this subcommittee with a list of "associated manufacturers", generic firms that manufacture drugs for brand name firms.

Third, wholly apart from the specific issue involving the drug companies' secret use of generic drugs produced by other manufacturers, the subpoena issued to me by the Commerce Committee raises a legal question regarding Section 301(j) of the Food, Drug and Cosmetic Act. That section restricts the disclosure outside the Department of trade secret data relating to manufacturing methods and processes.

Some of the material sought from this Department is trade secret data, as you noted yesterday Mr. Chairman. The Department of Justice has issued an opinion concluding that I would violate a criminal statute passed by the Congress if I transmitted trade secret data covered by Section 301(j) to

the Subcommittee. As an employee of the Executive Branch, I am bound to follow the Justice Department's interpretation of the law. But I would stress that we will make available to the Subcommittee all confidential information that is outside the scope of Section 301(j).

There is no question of separation of powers involved here. There is no question of executive privilege involved here. The Congress has the power to change the statute which prevents me from complying fully with the subpoena.

Mr. Chairman, before discussing these points in greater detail, I would like to make a preliminary observation. In 1976, while I was a private lawyer, I was privileged to represent this Subcommittee in a case called Ashland Oil, Inc. v. Federal Trade Commission. Although that case did not involve any conflict between the Legislative and Executive Branches regarding an interpretation of statute, it did involve the right of this Subcommittee to trade-secret data gathered by the FTC. Under a different statute from the one that binds me here today, we were successful in vindicating the right of this great Subcommittee, and the Congress, to the information.

I am sure we all appreciate the irony of my appearance before you today. Indeed, because of my former representation of you. I was sufficiently concerned that I considered disqualifying myself because of an appearance of a conflict of interest. Upon advice of counsel that there is no technical conflict, I have decided, however, that I should respond to the subpoena and explain our position on the issues raised.

Let me discuss in greater detail the two questions -- one involving a matter of drug policy, the second involving an issue of law -- that are the focus of this hearing.

Drug Policy: The "Man-in-the-Plant" Practice

As I have noted, underlying the subpoena is the Subcommittee's desire to investigate the so-called "man-in-the-plant" practice.

Under this practice, a brand name drug firm arranges for a generic manufacturer, who usually is not well known to the public, to manufacture drugs, which the brand name firm then sells to the public under its own label and at a premium price. To have some basis -- frequently slender -- for claiming that it manufactured the drug, the brand name firm

sends its representative ("the-man-in-the-plant") to the generic firm to "supervise" its operations.

The drugs are in fact manufactured on the premises of the generic firm, with its equipment and by its employees. Off the same assembly line can come two identical products -- a generic drug and a far more expensive brand name drug. Sometimes the same brand name firm conducts promotional campaigns in which it disparages generic manufacturers as a class, and urges consumers to place their trust in its brand name label.

As you know, Mr. Chairman, both FDA Commissioner Kennedy and I are deeply concerned about promoting the use of less expensive generic drugs as an important element in our national health policy. The Department has taken a number of actions to reduce the cost of medical care by encouraging the purchase of generic drugs because the evidence available convinces us that, in general, generic drugs of modern approval status are therapeutically equivalent to brand name products.

- We have announced that we will publish in January a comparative price list of different brands of prescription drugs and send it to all doctors and pharmacists in the Nation.

- We have helped New York State to prepare a list of therapeutically equivalent drugs and launch its drug substitution program.

- We are working with the Federal Trade Commission to develop a model generic drug substitution law for consideration by State legislatures.

- Our proposed Drug Regulation Reform Act of 1978, H.R. 11611, provides for a federal drug compendium, and contains other provisions designed to facilitate the use of generic drug products.

Thus, we are firmly committed to a policy of encouraging the use of generic drugs. This hearing will help promote that policy by making the public aware that advertising claims of brand name superiority generally have no basis in fact. By focusing additional public attention on this matter, the Subcommittee is performing a useful public service.

Moreover, Mr. Chairman, our Drug Regulation Reform Act deals directly with the man-in-the-plant problem.

Section 147(a)(2) of that bill requires that each drug product disclose the name of the actual manufacturer on the container. Thus, the brand name manufacturers will be required to disclose publicly when their brand name products are, in fact, manufactured by generic producers.

Finally, I would emphasize that, since the Subcommittee launched its investigation of this practice, we have sought to cooperate to the fullest extent that the law permits.

At an early point, the staff informed us that the Subcommittee's primary interest is in obtaining lists of "associated manufacturers," the generic firms who manufacture drugs for brand name firms.

I am pleased to announce that we are today giving to the Subcommittee a preliminary list, containing all the information that we have been able to compile in the few days since receipt of your subpoena. This list shows the brand name manufacturer, the drug involved and the "associated manufacturer" who may be manufacturing the drug for the better known company. We expect to be able to complete this listing within 30 days, and we will turn it over to the Subcommittee as soon as it is available.

I believe that this information will help the Subcommittee to conduct a full and thorough investigation of the man-in-the-plant practice.

Legal Issue Raised By The Subpoena

Let me turn now to the specific legal issue raised by

the subpoena. As I have noted, the subpoena requests copies of all Abbreviated New Drug Applications (and supporting forms and attachments) filed with the FDA since 1965 by thirteen named drug companies. Among other things, these documents contain detailed descriptions of the methods and processes involved in the manufacture of drugs by these drug companies. There is no question that these detailed descriptions constitute trade secrets concerning manufacturing methods and processes.

Section 301(j) of the Federal Food, Drug and Cosmetic Act specifically prohibits any HEW employee from disclosing any information concerning any method or process, which as a trade secret is entitled to protection, to any person

> ". . . other than to the Secretary of officers or employees of the Department, or to the courts when relevant in any judicial proceeding under this Act . . ."

Because of the importance of this issue, and because of our desire to provide access to the requested records if at all possible, the Under Secretary requested the opinion of the Attorney General (see attachment) as to whether, under Section 301(j), HEW officials may disclose the trade secret material sought by this Subcommittee.

In a response to that request, dated August 9, 1978, a copy of which is attached to my written statement, Acting Attorney General Michael J. Egan unequivocally stated that Section 301(j), by its terms, prohibits any official of HEW "from disclosing to a congressional committee trade secrets" contained in the documents specifically cited in the subpoena. He stated that turning over trade secrets to this Subcommittee in violation of Section 301(j) is a criminal offense, carrying a penalty of up to one year in prison and a $1000 fine.

In light of this statutory prohibition enacted by the Congress as part of the Federal Food, Drug and Cosmetic Act, and in light of the interpretation by the chief legal officer of the Executive Branch, I am thus unable to comply fully with the subpeona. As I indicated above, we stand ready to comply with the subpoena to the fullest extent possible, short of revealing trade secrets contained in the documents provided to FDA by drug manufacturers relying upon 301(j)'s prohibition against disclosure.

In conclusion, Mr. Chairman, I wish to underscore my strong personal belief in open government. For example, the Administration's proposed Drug Regulation Reform Act includes a provision (Section 111(j)), strongly opposed by the drug industry, that safety and efficacy data submitted in support

of an application for approval of a new drug would be disclosed to the public. The bill also would -- for the first time -- open up the drug approval process to effective public participation and public scrutiny.

Mr. Chairman, we wish to cooperate with the Subcommittee in every way possible to achieve our shared objectives.

Thank you.

Office of the Attorney General
Washington, D. C. 20530

9 AUG 1978

Honorable Hale Champion
Under Secretary
Department of Health, Education,
and Welfare
Washington, D.C. 20201

My Dear Mr. Under Secretary:

You have asked for my opinion whether the Department of Health, Education, and Welfare (HEW) may lawfully disclose to a congressional committee certain information in the Department's possession acquired from drug manufacturers pursuant to the provisions of the Federal Food Drug and Cosmetic Act, 52 Stat. 1040, as amended, 21 U.S.C.§§ 301 et seq. You state, and we assume for purposes of this opinion, that the House Committee on Interstate and Foreign Commerce has officially demanded information some of which constitutes trade secrets falling within the terms of section 301(j) of the Act, 52 Stat. 1042, as amended, 21 U.S.C. § 331(j).

It is my conclusion that section 301(j) by its terms prohibits you, or any other official of HEW, from disclosing to a congressional committee trade secrets, acquired pursuant to the sections cited therein. The section explicitly provides:

> The following acts and the causing thereof are hereby prohibited:
>
> * * * *
>
> (j) The using by any person to his own advantage, or revealing, other than to the Secretary or officers or employees of the Department, or to the courts when relevant in any judicial proceeding under this Act,

> any information acquired under authority of sections 404, 409, 505, 506, 507, 510, 512, 513, 514, 515, 516, 518, 519, 520, 704, 706, or 708 of this title concerning any method or process which as a trade secret is entitled to protection.

Disclosure of such information in violation of the terms of section 301(j) is a criminal offense. § 303, 52 Stat. 1043, as amended, 21 U.S.C. § 333(a).

Where an agency is barred by statute from disclosing certain information, congressional committees have no right to that information unless there is a clearly expressed congressional intent to exclude committee access from the general restriction on disclosure. This issue is by no means a new one. In 1975 Attorney General Levi, relying on opinions of his predecessors, opined that a House committee's subpoena served on the Secretary of Commerce did not override the confidentiality requirement of section 7(c) of the Export Administration Act of 1969, 83 Stat. 845, 50 U.S.C. App. 2406(c), 43 Op. A.G. No. 4 (1975).*/ Attorney General Levi, in reaching this view stated:

> Somewhat similar issues have been considered by prior Attorneys General. See, e.g., 27 Ops. A.G. 150 (1909) (subpoena of Senate committee for confidential information held by the Commissioner of Corporations); 41 Ops. A.G. 221 (1955) (request

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*/ Section 7(c) reads, in pertinent part, as follows:

> No department . . . or official exercising any functions under this Act shall publish or disclose information obtained hereunder which is deemed confidential . . . , unless the head of such department . . . determines that the withholding thereof is contrary to the national interest.

of Senate committee for confidential information held by the Federal Communications Commission); 42 Ops. A.G. no. 46 (1974) (request of House committee for tax return information). The foregoing opinions have proceeded under the general assumption --which I share--that statutory restrictions upon executive agency disclosure of information are presumptively binding even with respect to requests or demands of congressional committees.

That this assumption accords with general legislative intent is demonstrated by the inclusion, in a number of statutes concerning confidentiality of information, of explicit exceptions for congressional requests. 1/ When, as in § 7(c), such an exception is not provided, it is presumably not intended.

1/ See, e.g., 49 U.S.C. 1504 (information obtained by the Civil Aeronautics Board); 7 U.S.C. 12-1 (Department of Agriculture information on boards of trade). Regarding the background of the latter statute, see Freeman v. Seligson, 405 F.2d 1326, 1340-46 (D.C. Cir., 1968).

See also the Freedom of Information Act, 5 U.S.C. 552(c). Id. at 3. [Emphasis added].

It should be noted that the statute at issue in that opinion was less absolute in its terms than section 301(j), since it permitted disclosure "in the national interest." In contrast, the only exception for disclosure outside HEW of the information covered by section 301(j) is disclosure to the courts when relevant to a judicial proceeding.

The Congress itself has taken a strong position in support of the confidentiality of information acquired by the government and protected by such absolute non-disclosure statutes. For example, section 9(a) of title 13 of the United States Code provides that Commerce Department officials

shall not divulge certain census information to persons outside the Commerce Department. It reads, in pertinent part, as follows:

> (a) Neither the Secretary, nor any other officer or employee of the Department of Commerce or bureau or agency thereof, may, except as provided in section 8 of this title --
>
> (1) use the information furnished under the provisions of this title for any purpose other than the statistical purposes for which it is supplied; or
>
> (2) make any publication whereby the data furnished by any particular establishment or individual under this title can be identified; or
>
> (3) permit anyone other than the sworn officers and employees of the Department or bureau or agency thereof to examine the individual reports.

Like the Federal Food, Drug and Cosmetic Act, the census provisions authorize the agency to compel individuals and businesses to disclose highly confidential data. 13 U.S.C. § 6(b). Accordingly, Congress has provided for the protection of census data, 13 U.S.C. § 9, and has made it a criminal offense for those obtaining the information to disclose it outside the Department. 13 U.S.C. § 214.

In St. Regis Paper Co. v. United States, 368 U.S. 208 (1961), the Supreme Court held that while federal agencies could not subpoena or otherwise obtain this confidential information from the Commerce Department itself, they could subpoena, from the submitting businesses, their copies of the reports filed with Census. Congress reacted promptly to this decision by passing "clarifying" legislation --

> * * * to provide specifically that company retained copies of census reports submitted to the Bureau of the Census shall have the same confidential status which is afforded to the original census reports submitted to the Bureau of Census.

Senate Report 2218, 87th Cong., 2nd sess. (1962). The legislation amended section 9(a) to add:

> No department, bureau, agency, officer or employee of the Government, except the Secretary in carrying out the purposes of this title, shall require, for any reason, copies of census reports which have been retained by any such establishment or individual. * * * [As amended by Public Law 87-913].

Thus, Congress made it clear that information compelled from business establishments, and declared under penalty of a criminal statute to be confidential, was not to be disclosed outside the receiving department **/ and that this restriction could not be evaded by subpoenaing copies of the compelled reports in the hands of the submitting business.

The parallel between the Census reports and the drug processing information protected by section 301(j) is striking. Both deal with highly sensitive and confidential matter which business establishments are required to submit to the government. Both are deemed sufficiently sensitive that Congress felt obliged to protect confidentiality not only by prohibiting disclosure but by doing so under pain of criminal sanction. In neither case has Congress seen fit to provide an express exemption for disclosure to congressional committees, as it had in the statutes cited in footnote 1 of Attorney General Levi's opinion, quoted above, or in the provisions of the Privacy Act, 5 U.S.C. § 552a(b)(9). Indeed, it is significant that section 301(j) explicitly provides for disclosure to one of the coordinate branches of government, i.e., the courts, but makes no comparable provision for disclosure to committees of the Congress.

It is my view that section 301(j) by its express terms forbids you to disclose trade secret information obtained under the provisions of the Federal Food, Drug and Cosmetic Act to which it refers, and that this prohibition extends to disclosures to committees of the Congress.

Respectfully,

Michael J. Egan
Acting Attorney General

**/ See also, United States v. Little, 321 F. Supp. 388 (D. Del. 1971), reaffirming the absolute confidentiality of census information.

THE UNDER SECRETARY OF HEALTH, EDUCATION, AND WELFARE
WASHINGTON, D.C. 20201

The Honorable Griffin Bell
Attorney General
Department of Justice
Washington, D.C. 20530

AUG 9 1978

Dear Judge Bell:

On July 11, the Subcommittee on Oversight and Investigations of the House Committee on Interstate and Foreign Commerce notified the Secretary that it was conducting an investigation into the regulation of drugs and requested access to certain records. On July 21, the Subcommittee requested additional records in connection with their investigation. The scope of the Subcommittee's requests are set forth in the enclosed letters. We understand that the Committee on Interstate and Foreign Commerce may issue a subpoena for those records.

Secretary Califano has disqualified himself from participation in this matter because, while in private practice, he represented the Chairman of the Subcommittee on Oversight and Investigations in litigation involving a similar matter. Responsibility for responding to the Subcommittee's requests and a subpoena, should it be issued, therefore rests with me.

It is my desire to be as cooperative as possible with the Subcommittee, and to provide access to the requested records if possible. However, I am advised by the General Counsel of the Department that some of these records contain information which constitutes a trade secret within the meaning of Section 301(j) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 331(j). I am further advised that I could be subject to criminal sanctions for disclosing such trade secrets in violation of the prohibitions of that section.

Accordingly, would you please advise me whether in the Justice Department's view disclosure of these records to the Subcommittee in response to the enclosed requests or to a subpoena is prohibited by Section 301(j).

Sincerely,

Hale Champion

Enclosures

Mr. COLLINS. Mr. Chairman, if I may be heard.

Mr. MOSS. Mr. Collins.

Mr. COLLINS. I would like to say a word on the other side.

Mr. MOSS. First, Mr. Secretary, the Chair has not yet concluded. The Chair has a need, as the Secretary well knows, to lay out very carefully the order of this committee and the reason for the order of this committee.

The Chair might state, Mr. Collins and Mr. Lent, that it is the understanding of the Chair that this matter was discussed thoroughly with the Secretary's counsel and we were told such a statement would not be offered here at this time.

Therefore, it came as a matter of surprise to the chair when the statement was not only offered but a request was made go beyond the discussion which has preceded it.

Mr. WAXMAN. While it may be a surprise that a statement is being offered, I thought the chair properly laid out in the record the refusal of the Secretary to comply with the subpena.

If we are now accepting as part of the record the Secretary's statement as to his reasons for refusing to comply with the subpena, I think it would be helpful, at least to this member, to hear from him and to have the opportunity to question him about his refusal.

I am very, very disturbed that the Secretary, who has called upon Congress to do something to control the inflation of health care costs, is not now willing to give Congress information about generic drugs which may well just be relabelled in order to jack up the price to the consumers.

I do not know exactly what the Secretary considers to be a trade secret. I would like to know whether having a person in a plant of a drug manufacturer only for the purpose of attaching new labels and increasing the price is considered a trade secret?

Not only in fairness, but I think it is also essential for us as members of the subcommittee who will be called on to vote on a very serious matter of contempt, to hear from the Secretary and have the opportunity to question him about some of these items.

Mr. MOSS. The Chair has no objection to hearing more fully from the Secretary. The Chair does want to point out, however, that in taking the position he has taken he is being very consistent, because at the time of the appearance of former Secretary Rogers Morton before the subcommittee I did not at that time, nor did the committee, ask for or insist upon according the opportunity for extended discussion of reasons for noncompliance.

It is in keeping with that sense of fairness, particularly in an area where I can be accused of partisan preference, that I have acted as I have.

I now recognize the Secretary for a statement.

Secretary CALIFANO. Thank you, Mr. Chairman.

Mr. Chairman, earlier this week I received a subpena dated August 4 requesting that I produce copies of "all Abbreviated New Drug Applications" and supporting forms and attachments filed by 13 drug companies since January 1965.

These documents are being sought because, as you stated, Mr. Chairman: "We have long suspected that a number of trade name drug companies put their trade names on drugs actually manufactured by

generic drug companies, resulting in higher consumer prices for the same exact drugs. HEW has the documents which might settle that question, and we intend to get them."

Mr. Chairman and committee members, it is important that we keep three points clearly in view.

First, the Commissioner of the Food and Drug Administration and I are deeply committed both to promoting the use of less expensive generic drugs and to ending the drug companies' practice of secretly marketing generic drugs produced by other manufacturers as their own, more expensive brand name products. We have taken actions to achieve both these goals.

Second, I have directed the Department to produce all the information that we can short of violating a criminal statute passed by the Congress. Indeed, I am today, pursuant to the subpena, providing this subcommittee with a list of associated manufacturers, generic firms that manufacture drugs for brand name firms.

Third, wholly apart from the specific issue involving the drug companies' secret use of generic drugs produced by other manufacturers, the subpena issued to me by the Commerce Committee raises a legal question regarding section 301(j) of the Food, Drug, and Cosmetic Act. That section restricts the disclosure outside the Department of trade secret data relating to manufacturing methods and processes.

Some of the material sought from this Department is trade secret data, as you noted yesterday, Mr. Chairman. The Department of Justice has issued an opinion concluding that I would violate a criminal statute passed by the Congress if I transmitted trade secret data covered by section 301(j) to the subcommittee. As an employee of the executive branch, I am bound to follow the Department of Justice's interpretation of the law. But I would stress that we will make available to the subcommittee all confidential information that is outside the scope of section 301(j).

There, as I indicated, is no question of separation of powers involved here. There is no question of executive privilege involved here. The Congress has the power to change the statute which prevents me from complying with the subpena.

Mr. Chairman, before discussing these points in greater detail, I would like to make a preliminary observation. In 1976, while I was a private lawyer, I was privileged to represent this subcommittee in a case called *Ashland Oil, Inc.* v. *Federal Trade Commission*. Although that case did not involve any conflict between the legislative and executive branches regarding an interpretation of statute, it did involve the right of this subcommittee to trade secret data gathered by the FTC. Under a different statute from the one that binds me here today, we were successful in vindicating the right of this great subcommittee, and the Congress, to the information.

I am sure we all appreciate the irony of my appearance before you today. Indeed, because of my former representation of you, I was sufficiently concerned that I considered disqualifying myself because of an appearance of a conflict of interest. Upon advice of counsel that there is no technical conflict, I have decided, however, that I should respond to the subpena and explain our position on the issues raised.

As I have noted, underlying the subpena is the subcommittee's desire

to investigate the so-called man-in-the-plant practice, which you and Mr. Waxman mentioned.

Under this practice, a brand name drug firm arranges for a generic manufacturer, who usually is not well known to the public, to manufacture drugs, which the brand name firm then sells to the public under its own label and at a premium price. To have some basis—frequently slender—for claiming that it manufactured the drug, the brand name firm sends its representative, the man-in-the-plant, to the generic firm to "supervise" its operations.

The drugs are in fact manufactured on the premises of the generic firm, with its equipment and by its employees. Off the same assembly line can come two identical products—a generic drug and a far more expensive brand name drug. Sometimes the same brand name firm conducts promotional campaigns in which it disparages generic manufacturers as a class, and urges consumers to place their trust in its brand name label.

As you know, Mr. Chairman, both FDA Commissioner Kennedy and I are deeply concerned about promoting the use of less expensive generic drugs as an important element in our national health policy.

We have announced that we will publish in January a comparative price list of different brands of prescription drugs and send it to all doctors and pharmacists in the Nation.

We have helped New York State to prepare list of therapeutically equivalent drugs and launch its drug substitution program.

We are working with the Federal Trade Commission to develop a model generic drug substitution law for consideration by State legislatures.

Our proposed Drug Regulation Reform Act of 1978, H.R. 11611, provides for a Federal drug compendium, and contains other provisions designed to facilitate the use of generic drug products.

Thus, we are firmly committed to a policy of encouraging the use of generic drugs. This hearing will help promote that policy by making the public aware that advertising claims of brand name superiority generally have no basis in fact.

Moreover, Mr. Chairman, our Drug Regulation Reform Act deals directly with the man-in-the-plant problem.

Section 147(a)(2) of that bill requires that each drug product disclose the name of the actual manufacturer on the container. Thus, the brand name manufacturers will be required to disclose publicly when their brand name products are, in fact, manufactured by generic producers.

Finally, Mr. Chairman, I would emphasize that since the subcommittee launched its investigation of this practice we have sought to cooperate to the fullest extent that the law permits.

At an early point, the staff informed us that the subcommittee's primary interest is in obtaining lists of "associated manufacturers," the generic firms who manufacture drugs for brand name firms.

I am pleased that we are today giving to the subcommittee a preliminary list containing all the information that we have been able to compile in the few days since receipt of your subpena. This list shows the brand name manufacturer, the drug involved and the associated manufacturer who may be manufacturing the drug for the better known company. We expect to be able to complete this listing within

30 days, and we will turn it over to the subcommittee as soon as it is available.

It is the first time this information, to our knowledge, has been made available outside the Department.

I believe that this information will help the subcommittee to conduct a full and thorough investigation of the man-in-the-plant practice.

Let me turn now to the specific legal issue raised by the subpena.

As I have noted, the subpena requests copies of all abbreviated new drug applications and supporting forms and attachments filed with the FDA since 1965 by 13 named drug companies. Among other things, these documents contain detailed descriptions of the methods and processes involved in the manufacture of drugs by these companies. There is no question that these detailed descriptions constitute trade secrets concerning manufacturing methods and processes.

Section 301(j) of the Federal Food, Drug, and Cosmetic Act specifically prohibits any HEW employee from disclosing any information concerning any method or process, which as a trade secret is entitled to protection, to any person "* * * other than to the Secretary or officers or employees of the Department, or to the courts when relevant in any judicial proceeding under this act * * *."

Because of the importance of this issue, and because of our desire to provide access to the requested records if at all possible, the Under Secretary requested the opinion of the Attorney General as to whether, under section 301(j), HEW officials may disclose the trade secret material sought by this subcommittee.

In a response to the request, dated August 9, 1978, a copy of which is attached to my written statement, as to the Justice Department opinion, Acting Attorney General Michael J. Egan unequivocally stated that section 301(j), by its terms, prohibits any official of HEW "from disclosing to a congressional committee trade secrets" contained in the documents specifically cited in the subpena. He stated that turning over trade secrets to this subcommittee in violation of section 301(j) is a criminal offense, carrying a penalty of up to 1 year in prison and a $1,000 fine.

In light of this statutory prohibition enacted by the Congress as part of the Federal Food, Drug, and Cosmetic Act, and in light of the interpretation by the chief legal officer of the executive branch, I am thus unable to comply fully with the subpena.

As I indicated, we stand ready to comply with the subpena to the fullest extent possible, short of revealing trade secrets contained in the documents provide to FDA by drug manufacturers relying upon 301(j)'s prohibition against disclosure.

As I indicated, I will submit to the committee tomorrow examples of expurgated forms you requested in the subpena, with the only information blacked out on the form being the manufacturing process within the scope of 301(j).

Mr. Moss. You will give us precisely what we could get without having any kind of a difference of opinion because it would be precisely useless. It gives us no information of the type the committee requires. It begs the question of the needs of the subcommittee.

I might add it is a most gracious act without the slightest bit of substance.

Secretary CALIFANO. Let me note that I do think what I have already submitted to counsel, which is a first preliminary list, we are giving you for the first time, the first time HEW has released it, a list of the manufacturers, brand name manufacturers, the associated manufacturers, and the brand name drugs that are manufactured.

Mr. Moss. While you are at it, supplying the material of help to the committee, would you also supply us with any cases where the courts have held that the opinion of the Attorney General is binding on another cabinet officer?

Secretary CALIFANO. I will have a memorandum supplied to the General Counsel.

Mr. Moss. I think it will be a fruitless search.

Mr. GORE. Do you agree that the information we are seeking would be helpful in your opinion? Would it be helpful to us in our effort to investigate this area and in our determination as to whether the law should be changed?

Secretary CALIFANO. Mr. Gore, I have my doubts as to whether or not this information about manufacturing processes would have any effect at all or be at all helpful to this committee in its investigation of the man-in-the-plant practices.

I would note, incidentally, in terms of making information public and making more information about safety and efficacy public, the Drug Reform Act proposed would make vast amounts of information in that area public which never before had been made public.

Mr. GORE. How can you compare different manufacturing processes if you cannot see them?

Secretary CALIFANO. You cannot, and you would have a problem doing that.

Mr. GORE. Then it is relevant information which would be helpful to us.

What we are seeking to do is to determine whether or not the public is being fleeced by a process whereby brand name drug companies are getting generic drugs and calling them special brand name drugs simply because they resort to the rule of having one of their employees stationed at the generic drug plant as the drugs are being made.

Secretary CALIFANO. Mr. Gore, we are providing to the committee everything in our records that identifies the brand name manufacturer, the associated manufacturer, and the drug which might be manufactured.

Mr. GORE. All that tells us is who the companies are. What we want to know is what the——

Mr. Moss. The Chair has been requested, and quite properly, to recess for 10 minutes so that members may respond to the quorum call.

I would hope everyone can return promptly at the conclusion of the quorum call so that we might continue.

The committee will stand in recess for 10 minutes.

[Recess taken.]

Mr. Moss. The committee will be in order.

Mr. Gore, I believe you were asking a question at the time we recessed.

Mr. GORE. Thank you, Mr. Chairman.

We are told, Mr. Secretary, by the large pharmaceutical companies that they are justified in charging a higher price to the public for these drugs because the manufacturing process is allegedly superior.

We have other information which leads us to believe that their claims are merely a sham, that all they do is put one of their employees in the factory of a generic drug manufacturer and resort to that man-in-the-plant rule in order to flimsily justify their claim of a superior manufacturing process.

We have asked you to give us information at your disposal which we believe will allow us to determine whether or not their manufacturing process is superior because they have one of their employees at that plant.

Earlier you were responding to my question about the legitimacy of our need for the information.

It seems to me, in light of those facts, that we deserve to have that information. I think it would clearly be helpful in our deliberations. I would be interested in why you disagree with that.

Secretary CALIFANO. Mr. Gore, let me make two points.

One, we are providing the committee with a list of the brand name manufacturers and the generic manufacturers associated with them so that the committee can determine which of those manufacturers are actually manufacturing brand name drugs as well as generic drugs.

In terms of manufacturing processes, the material the committee has subpenaed will provide the manufacturing process in every case of the brand name manufacturer. However, the way the subpena is currently drafted, it will not necessarily acquire for the committee the manufacturing process of the associated generic manufacturer.

Mr. GORE. That would still be helpful, if I might say so, because it would tell us what role is being played by the employee of the manufacturer of the brand name company in the plant of the generic manufacturer. Therefore, I think it is clearly helpful.

Secretary CALIFANO. It might provide that.

Let me make one other point. I want to make our position clear.

We are in no way implying nor indicating that we think there is something inferior about the manufacture and processes of generic manufacturers, those processes filed with the FDA meeting all the standards of brand name manufacturing processes. I do not want that implication.

Mr. GORE. Mr. Secretary, in our society, laws, principles, and rights are often in conflict. We have two in conflict in this instance.

On the one hand we have article I of the U.S. Constitution. On the other hand we have section 301(j) of the Federal Food and Drug Cosmetic Act.

You have chosen to place more importance on section 301(j) of the Federal Food and Drug Cosmetic Act than on article I of the U.S. Constitution.

Section 301(j) was intended primarily to prevent employees and inspectors of the FDA from selling information to competitor drug companies. The Congress clearly never intended to exclude itself from the right to receive information that is given to the Secretary pursuant to the Food and Drug Act.

In light of your expertise in this area, in light of your experience in working on the *Ashland* case, in light of your knowledge of the

precedent involved here, I am interested in a candid response from you as to whether or not you personally agree with the opinion given you by the Acting Attorney General.

Secretary CALIFANO. Mr. Gore, I am not my own lawyer in this situation. The Attorney General of the United States is the lawyer. I abide by his opinion. I have not done any legal research on this particular statute.

I sit here not as a lawyer but as custodian of the records and as Secretary of HEW.

Mr. Moss. The time of the gentleman has expired.

The Chair wants to announce that he will this morning hold tightly to the 5-minute rule.

The Chair now recognizes the gentleman from Texas, Mr. Collins.

Mr. COLLINS. Thank you, Mr. Chairman.

Mr. Secretary, I opposed this subpena. I want to say that the chairman, as he mentioned earlier, has been very consistent. He has very strong feelings on this subject, the rights of the subcommittee and the rights of Congress. We went through this before with another member of the cabinet.

Knowing, as you said, that you are an attorney but that you are not appearing before us today as an attorney, I hope you will continue the same aggressiveness and fairness you have a reputation for. There is a key issue involved here.

You are governed by the advice of your counsel, who is the Attorney General of the United States. I notice here that he specifically states, "Where an agency is barred by a statute from disclosing certain information, congressional committees have no right to that information."

He goes on to say, "Disclosure of such information in violation of the terms of section 301(j) is a criminal offense against you."

We have a very vital subject involved here. You have gone ahead and disclosed information that is, and probably rightly so, information that should be public information and certainly congressional information.

However, to take these trade secrets, which is what you have not disclosed, and which you have said are covered under the statute, which involve manufacturing processes, it would be going beyond your jurisdiction.

I am not a lawyer, but I heard my colleague express himself. He quoted something. The Constitution states that there are three branches of Government—the executive, the judicial, and Congress. You represent the executive branch and you are not subservient to Congress.

How deeply have you studied this case? You said you were not your own lawyer on this case, but——

Secretary CALIFANO. I have not gotten into a legal research in this case. I have accepted the opinion of the Attorney General because he is the lawyer for the executive branch.

Mr. COLLINS. Until you are advised otherwise by the Attorney General you will stand by this same position?

Secretary CALIFANO. I will, yes.

Mr. COLLINS. Of course, what is involved here is whether or not we are going to take trade secrets which have built up the greatest chemical and pharmaceutical business in the world, and where we have made

tremendous breakthroughs here because of the secrets and the research and development done, and if we turn research and development of private companies into general information we are going to lose every bit of that.

The cost of research and development does not go into the direct cost of manufacturing. Of course, you will not be involved in the economics of this, I understand.

One further thing. You said you strongly believe in making these generic drugs available to the public. Do you see any hesitancy or reluctance at this time? Have you done anything to slow down this process in HEW?

Secretary CALIFANO. No; as I indicated in my statement, we have taken several steps which never have been taken before to make generic drugs more widely available and to make the pricing of drugs more well-known to the consumers and to the doctors who are prescribing the drugs.

Mr. COLLINS. Do you believe it is essential in your department that this information be made public or do you see any advantage in giving it out?

Secretary CALIFANO. The manufacturing process information?

Mr. COLLINS. The trade secrets, manufacturing processes.

Secretary CALIFANO. I should note that section 301(j) prohibits the disclosure of trade secrets involving manufacturing processes. There is trade secret information that we will——

Mr. MOSS. If the gentleman will yield.

Mr. COLLINS. I will be glad to.

Mr. MOSS. Also does it not provide, Mr. Secretary, "except as authorized by an officer of the Department"—including you?

Secretary CALIFANO. Well, that is one of the issues of interpretation, Mr. Chairman.

Mr. MOSS. I realize that, but it is not black and white, is it, Mr. Secretary? Just a reading on its face, it is not just black and white.

Secretary CALIFANO. The black was written on the white for me in the Attorney General's opinion.

Mr. MOSS. You are relying on the interpretation and not just a plain reading of the statute.

Secretary CALIFANO. Well, he feels that a plain reading of the statute does that.

Mr. MOSS. When we talk of the Attorney General we are not talking of the one who was confirmed as the Attorney General but that one strange fellow over there that none of us know by the name of Egan who prepared the opinion, and, as I stated, not in too scholarly a fashion.

I thank the gentleman for yielding.

Secretary CALIFANO. If I may just, aside from the interpretation of this part of the statute, make clear to Mr. Collins that section 301(j) applies to trade secret information regarding manufacturing processes. It does not apply to other trade secret information on its face.

Mr. COLLINS. As I read the statute, and I am not a lawyer, but you are advised by the lawyer for the United States, the Attorney General, Congress, when it passed the law which governs this subject, states that these trade secrets will not be made public. It does not say made public to anybody. It says they will not be made public.

I hope you hold firm on this. If we start releasing all research and confidential data it would be just like a lawyer turning over all of his work papers.

Mr. MAGUIRE. Does the gentleman equate the supply of information to this subcommittee with release of information to the public in view of the record of this subcommittee in keeping confidential documents confidential unless and until the subcommittee votes otherwise?

Mr. COLLINS. The record of this subcommittee has been exemplary, but we never have been as hard-pushed as we have on trade secrets of drugs.

Mr. Moss. If the gentleman would yield further.

Mr. COLLINS. Yes.

Mr. Moss. Were we not pushed even further on the Arab boycott issue?

Mr. COLLINS. We had a gentleman from New York who discussed it in the paper.

Mr. Moss. Not a member of this subcommittee. Nor was it material that we had subpenaed.

Mr. COLLINS. The chairman and this subcommittee have been good, but that issue of the Arab boycott was leaked. The Armed Services Committee set a poor record.

However, this is a sensitive area.

Mr. MAGUIRE. If the gentleman would respond to my question. I take it the gentleman does not equate those two things?

Mr. COLLINS. What things?

Mr. MAGUIRE. Revealing information to the public on the one hand and providing information to this subcommittee in pursuit of its responsibilities on the other.

Mr. COLLINS. My basic issue here is that we have three branches of Government: Congress, the executive, and the judiciary. I believe we are trying to make the executive subservient to Congress, which is wrong.

Mr. Moss. The time of the gentleman has expired.

Mr. Waxman will be heard from next.

If I might first make this correction. The list of companies mentioned in the subpena is about evenly divided between the trade name and the generic name manufacturers, so that the answer to Mr. Gore's question is that the material we have subpenaed would illustrate the true facts given the problem discussed.

Secretary CALIFANO. To the extent they match up, Mr. Chairman. My only point was——

Mr. Moss. Mr. Secretary, I want to assure you that we have excellent investigators. They match beautifully.

Mr. Waxman?

Mr. WAXMAN. Thank you, Mr. Chairman.

Mr. Secretary, you told us in your statement that you think we ought to move to generic equivalents as a way of saving the taxpayers and the consumers money in the purchase of drugs. In the drug reform bill you are supporting and which you are asking Congress to approve, you also recognize that generic distinction.

However, it is not a universally held opinion that generic drugs are equivalent. We have the drug industry telling us that there are better quality drugs which are manufactured by a special process which entitles them to more money.

The question I have for you is how we, as Members of Congress, can deal with the legislation you are proposing to us on drugs, on medicaid and on cost containment if we are not entitled to review information that you have which would show whether those drugs are equivalent in terms of quality.

Secretary CALIFANO. Mr. Waxman, my only response to that is that the Congress can change section 301(j). It is a matter of what that statute states.

Mr. WAXMAN. You are a very distinguished lawyer. In fact, you have represented this subcommittee, which you said might well have put you in a conflict situation. I think you have even represented a number of drug manufacturers. I do not think that would have put you in a conflict position any more than having represented this committee.

However, you are personally responsible for either a criminal citation, as you seem to think the Attorney General's opinion would indicate, or a contempt of Congress citation.

It seems you are not taking that responsibility seriously in determining by yourself as a lawyer whether the Congress is entitled under the Constitution to this information. You are relying on some clerk in the office of the Attorney General to give you an opinion which you feel bound by.

You are the one responsible. I would like you to do the research and come up with a legal opinion which would indicate whether your actions are consistent with your obligation as Secretary.

Secretary CALIFANO. Mr. Waxman, I am not my own lawyer in this situation. There are sayings about lawyers who have themselves for clients.

Second, I did call Attorney General Bell this morning, mindful of the importance of this hearing, to be sure that he understood and was aware of the opinion Mr. Egan signed. He was and he agreed with it. He indicated that to me.

Mr. WAXMAN. Are you legally bound by an opinion of the Attorney General as to your conduct for which you would be criminally liable?

Secretary CALIFANO. The Attorney General sent me an opinion saying if I released this information, I would commit a crime subject to fine and imprisonment. I think he is the Nation's chief prosecutor. I should take him seriously.

Mr. WAXMAN. I would not discard the fact it should be taken seriously.

We have the Congressional Research Service telling us that the Constitution requires you to give us this information and you could be held in contempt should you refuse. You should take that seriously, also.

I think that you ought, as a lawyer, to do the research and look at these precedents and decide whether the clerk in the Office of the Attorney General is giving you advice to which you ought to be bound.

You are not legally bound by an opinion any more than your clients are obligated by law to follow your advice.

Secretary CALIFANO. I would draw a distinction between an ordinary lawyer-client situation and the Attorney General's opinion in a situation like this.

An ordinary lawyer-client situation is such that the client can do whatever he or she wants to do, of course, regardless of what the lawyer recommends.

This is not a situation where a lawyer is recommending something to me. This is the Attorney General not advocating any case for or against me. Indeed, if one looks at the letter that we sent to the Attorney General asking for the opinion, we said we are disposed to provide as much information as possible to the subcommittee.

The function of the Attorney General is to interpret the law and determine what he thinks is right, what he thinks is the correct interpretation of the law, and he has rendered that opinion.

Mr. WAXMAN. Are you aware that the same Attorney General who has given you this opinion would be mandated by law to pursue your prosecution should Congress hold you in contempt?

Mr. Moss. Would the gentleman yield?

Mr. WAXMAN. I would be pleased to yield.

Mr. Moss. I hold the intriguing thought that perhaps, rather than relying upon that Attorney General or one of his clerks, we might use the older powers of the House to directly proceed on contempt.

The time of the gentleman has expired.

The Chair now recognizes the gentleman from Pennsylvania, Mr. Marks.

Mr. MARKS. Thank you, Mr. Chairman.

Mr. Secretary, I am deeply concerned about what appears to be a confrontation. The longer that confrontation goes on, the more difficult it would be to extricate either yourself or ourselves, the Attorney General, or anyone else who might be involved.

When I came in here this morning, I was not at that time totally convinced in my own mind that the information we sought, which you suggest you cannot give, was vital to our investigation.

However, in discussing certain aspects of this matter with other members of the subcommittee, I might say on both sides, it appears there is a serious concern that unless we have more information than you are willing to provide at this moment concerning the manufacturing process, that we will not have enough information to complete this investigation, at least not in the fashion we have the responsibility to complete it.

I am now wondering whether or not there is not some middle ground which we can take, and which has been done in the past, which will provide you the opportunity of giving us at least enough information to prevent this confrontation of being embarrassing to you, your office, the executive branch, and to ourelves.

I do not know how those things are worked out really, but I suspect there must be a way.

Having said that, I am wondering whether there is not under the present situation information concerning the manufacturing process that you could provide to this subcommittee, which we would keep confidential, which would give us enough information to proceed with our investigation and bring it to some reasonable conclusion.

Secretary CALIFANO. Mr. Marks, let me say in response to that—let me underline one thing—I have no question about this committee's keeping information confidential. Your record is impeccable. We have reviewed the record of this committee when I was counsel for it, and

there has not been a single instance of any violation of that kind of trust. There is no question about that.

What you can do is to take the names of the manufacturers we have provided and the associated manufacturers we have provided and subpena them directly for the manufacturing process information that you need. I think that would create no problem in section 301(j) and would avoid any confrontation between the legislative and executive branches.

Mr. MARKS. Might I ask counsel whether or not that is possible?

Mr. ATKISSON. You mean to subpena the companies directly?

Mr. MARKS. Yes.

Mr. ATKISSON. It certainly is. I believe the companies would have no legal ground to stand on whatever in defiance of our subpenas. It flies in the teeth of the idea, however, that the Congress would exclude itself from the very same information conveniently in the hands of the Secretary which is only down the block here.

Mr. MARKS. I appreciate what you are suggesting to us.

On the other hand, and as much as there seems to be some question in the minds of some people on this committee that this situation may not be all one way or the other, is that not a way of getting the information without provoking a constitutional confrontation?

Mr. MOSS. If you would yield.

Mr. MARKS. I would be delighted.

Mr. MOSS. This issue has many, many ramifications. There are well over 100 similar statutes running the road gamut of governmental actions involving executive departments and agencies of the Government.

If the Congress were to suffer this kind of construction of the statute, as erecting a barrier against its access to information, I think we would be opening a pandora's box, potenttial for litigation, and for endless frustration of congressional inquiry which would be beyond belief.

It is for that reason I believe we must meet the challenge at the moment it is raised.

Mr. MARKS. I can appreciate what you are saying, Mr. Chairman, and I understand the problem that presents.

On the other hand, we have a situation here I am not sure is dissimilar to others but at least to some extent we are both, this committee and the Secretary and HEW, working toward the same end.

In light of the fact we are working to get to the same point, we are not opposed to one another and we want an answer to these problems and we want to remedy the situation, which is a bad one. I am wondering whether at this point we need to have this constitutional confrontation.

Mr. MOSS. If the gentleman would yield further.

Mr. MARKS. I would be glad to.

Mr. MOSS. The Chair, with some reluctance, makes this observation: We are not really dealing with a problem of the Secretary. We are dealing with the problem of the Attorney General who, during my 26 years in the Congress, constitutes the most extreme case of reluctance to deal fairly and openly with the Congress that I have ever encountered.

I have more than a passing acquaintance with other Attorneys General. During the years I investigated in preparation for the writ-

ing of the Freedom of Information Act, I dealt with a number of Attorneys General. The present occupant of the Office of the Attorney General seems to have an absolute determination that whenever he can block the Congress from getting anything he will do so. That is what we are confronted with here now, the intransigence of the Attorney General of the United States, not the intransigence of the Secretary of HEW.

Mr. MARKS. Mr. Chairman, again I do not dispute what you are suggesting. I do suggest, however, that whatever additional information we secure today, that perhaps before we take any additional action that we bring the Attorney General before us at this particular point nad see what develops then.

Mr. MOSS. We have no jurisdiction over the Attorney General.

Mr. WAXMAN. If the gentleman would yield, I think it would be inappropriate to bring the Attorney General before us when the potential contempt is against the Secretary of HEW.

Mr. MARKS. Based on the Attorney General's decision, however, which he feels he must follow.

Mr. WAXMAN. You do not bring in an attorney to question why his client is breaking the law, even if it is on the advice of counsel.

I think the Secretary of HEW, Mr. Califano, obviously is responsible for his own conduct and his own actions. Legally he is caught in a difficult situation where he believes, according to an Attorney General's opinion, that the statute tells him he would be liable if he gives us the information, and we believe he would be liable if he does not.

Mr. MARKS. If I may interrupt for a moment.

Mr. WAXMAN. It is your time.

Mr. MARKS. We have a situation where it is a statute which we could, if we desired, change. However, in doing that we run into the same problem—that it might be necessary to do this in over 100 other statutes.

Then we come back to the constitutional confrontation. What I am suggesting is that perhaps it woud not hurt, before we go much further, if we bring the Attorney General before us, should we be able to do so and he agrees to come, in an effort to discuss with him openly his basis for the constitutional problem he presents to us and to the Secretary.

Mr. WAXMAN. It is really a confrontation of the legislative branch as opposed to the executive branch. We have so many statutes that talk about confidentiality of information.

If that argument is used as a way of keeping Congress from getting information which we will have to know about if we have to pass additional information or if we want to exercise our oversight function, we will have this continual confrontation.

The executive branch has ways of getting together through Cabinet meetings, and the President can resolve differences between the various Cabinet officials. They can resolve those problems.

As much as I would like to compromise the situation, I cannot see our bending in this particular circumstance because then we are setting a precedent where Congress will forever after be told that we can take some middle course and not get that information to which we are legally entitled.

Mr. MARKS. The gentleman points up a problem which I acknowledge.

Mr. Moss. The Chair wants to state that the time of the gentleman has expired.

The Chair makes this additional point. In dealing with the problem of contempt by this committee it can be handled very quickly through the House and through the parent committee because it is cloaked with the highest privilege of the House.

To follow the suggestion of the Secretary that we rewrite the statute would be needless and time consuming and not privileged activity which could involve a year or two during which we are effectively estopped from any hope of completing an investigation which, given the information we seek, can be concluded within about 8 weeks.

Therefore, there is a very practical reason that we should proceed in this fashion.

While the precedents are clearly on our side for subpenaing the material directly from the manufacturers, one of the best cases being the case of *Ashland*, beautifully briefed and before us for review, nevertheless we could be endlessly harassed in a number of Federal district courts around the country, again losing valuable time from the labors of the committee.

I would point out that we have moved substantially ahead of the Department in narrowing our request. We have for over a month attempted to negotiate this so that we could be accommodated and the Department could also be accommodated.

There has been an unyielding position on the part of the Department. The heart of what we want is what we must have in order to be insured of the ability to make an independent judgment.

Briefly, Mr. Lent?

Mr. LENT. I just wanted to set the record straight. You indicated that this particular Attorney General was difficult.

In 1975, we had another situation involving the then-Secretary of Commerce, Rogers Morton, a similar confidentiality statute applicable to another circumstance.

Other than that, however, it was on all fours with this case. We had a very distinguished Attorney General then, as we do today, Attorney General Levi, who wrote an opinion cited in this Attorney General's opinion, which raised exactly the same issues.

As a matter of fact, what the Congress did then was to change the law.

Mr. Moss. If the gentleman would yield, I would point out we then—if you are talking about Mathews?

Mr. LENT. Section 7(c) of the Export-Import Act.

Mr. Moss. We cited the Secretary for contempt, and the morning it was scheduled to come up in the full committee, he surrendered the material to the committee.

Mr. LENT. That is correct, Mr. Chairman.

Mr. Moss. We subsequently dealt with the statute.

Mr. LENT. And subsequently, in statute 235, in 1977, we amended section 7(c) of the Export-Import Act. The citation is in our own Congressional Research Service brief.

Mr. Moss. I pointed out, however, that after and not prior we cited the Secretary——

Mr. LENT. We saw the wisdom of changing the statute.

Mr. Moss. We had an opportunity.

Mr. LENT. We carved out an exception so that henceforth the Secretary of Commerce must respond to subpenas for this type of material.

We could do that again, as Mr. Marks has pointed out.

Mr. Moss. That is commendable, but we carved out the opportunity from something already moving through the legislative process.

The report on the amendment states that, "This amendment should not be necessary. It is made necessary only by the decision of the executive branch to interpret section 7(c) in a manner inconsistent with the intent of the Congress."

I might add this would also be made necessary only because of the desire of the Attorney General to interpret this in a manner inconsistent with either the intent or the needs of the Congress.

Mr. Maguire?

Mr. MAGUIRE. Thank you, Mr. Chairman.

Mr. Secretary, I am concerned not only about the constitutional issue involved and the rights and responsibilities of the people of this country as they are expressed through the Congress of the United States and this committee, but also about the need to straighten out the problem as to what is and what is not proper in regard to generic and brand name drugs.

My understanding, based on statements which Commissioner Kennedy has made before the Senate and on information which I have received more recently, is that FDA in fact is having a great deal of difficulty developing regulations which restrict misleading procedures with respect to the manufacturing of brand and generic drugs without interfering with what FDA regards as legitmate and often necessary practices. Is that correct?

Secretary CALIFANO. I am not familiar in detail with the problems they are having. I know we are looking into this area. I know we are looking into the extent to which we can tighten regulations in this area. That is one of our objectives.

Mr. MAGUIRE. But it has dragged on now for a period of time, and there seems to be no answer.

Secretary CALIFANO. That would not distinguish it from other things in HEW.

Mr. MAGUIRE. That is fine. You said that, I did not.

The other thing is that both you and we are presently working on a major reformulation of drug legislation.

Secretary CALIFANO. That is correct.

Mr. MAGUIRE. In light of all that, it seems to me to be particularly important that the Congress have access to the information which I think any reasonable person would agree would be required for sensible legislating in this area. Would you care to comment on that?

Secretary CALIFANO. Mr. Maguire, I am not arguing about relevance or irrelevance of the information through either this committee's investigation particularly of the man-in-the-plant practices in the pharmaceutical industry or to the general problem of the full committee in connection with the drug reform legislation the committee is now drafting. I am simply complying with the statute in the manner the Attorney General has indicated I should comply with it. I am not disputing nor arguing whether this information is relevant or irrevelvant.

Mr. MAGUIRE. With respect to the question I asked Mr. Collins earlier, whether he saw any distinction between releasing the material "to the public" and releasing material to a duly authorized committee of the Congress in pursuit of its investigative responsibilities, I would like to ask you the same question—whether you see any distinction between those two. There does not appear to be a distinction in the opinion of the Attorney General.

Secretary CALIFANO. In the context of section 301(j), there may not be a distinction. In the context of the statute involved in the *Ashland* case, the statute there prohibits the disclosure to the public, and the court indicated that that prohibition did not apply to the Congress.

Here the prohibition is against disclosure other than to the Secretary or officers, or employees of the Department or to the courts when relevant in any judicial proceeding under this act, so the statute is somewhat different from the statute in the *Ashland* case.

Mr. MAGUIRE. You never refer in your statement, nor even now, in discussing this, to the phrase which appears in the law quite clearly, I think qualifying the entire section, the phrase which refers to "for advantage." Is that a deliberate omission on your part?

Secretary CALIFANO. No; the statute states, "Using by any person to his or her own advantage, or revealing other than to the Secretary or to the courts."

In the opinion of the Attorney General, Mr. Egan's opinion which the Attorney General has blessed, it reads that as saying that revealing is an independent clause. I refer to the "revealing other than to the Secretary."

Mr. MAGUIRE. Surely there is no way that your provision of material to this duly authorized subcommittee could be deemed to be an action taken by you to your own advantage.

Secretary CALIFANO. No; I absolutely do not think that.

Mr. MAGUIRE. I would point out that the *Ashland* case to which you referred does, in fact, make a distinction between provision of material to the public and to the Congress. The court found in the *Ashland* case that Ashland had not made the requisite showing of a real likelihood of injury. It found that the transfer of data from the FTC to the subcommittee does not lead inexorably to either public dissemination or disclosure to Ashland's competitors.

Moreover, the courts must presume that the committees of Congress will exercise their powers responsibly and with due regard for the rights of the affected party.

Does that not have some relevance to the matter before us?

Secretary CALIFANO. Mr. Maguire, the statute in *Ashland* prohibited disclosure "to the public." That phrase was an issue in that case.

This statute does not have a phrase like that.

Mr. Moss. Mr. Lent?

Mr. LENT. Thank you, Mr. Chairman.

I know this Congress was in a lot of trouble, but when the chairman of the distinguished committee who is a legislator of great renown says in effect it is easier and more expeditious to hold a Cabinet officer in contempt than to change a statute by adding four words to it I think it is a tragedy.

What we have here is a situation exactly parallel, as I see it, to the one we were confronted with in 1975 when then-Secretary of Commerce Rogers Morton was before us, where we had subpenaed material from him having to do with the Arab boycott of Israel. He refused to turn that over, citing section 7(c) of the Export Administration Act of 1969.

At that time, and then as now, we had a letter from the Attorney General saying that because of the confidentiality provision which applied the Secretary should not turn that information over to the Congress.

Now, it is true that ultimately Secretary Morton did surrender the documents which the committee had subpenaed, but it is also true that Congress then changed section 7(c) of that statute to provide an explicit exception similar to the exceptions we have in the laws governing the operation of the CAB, the Department of Commerce with respect to census information, the Department of Agriculture with respect to boards of trade, saying in effect that the confidentiality provision would not apply to requests of the Congress of the United States.

The present statute states that "This information which the Secretary has in his possession cannot be turned over to anyone," and it further reads, "often than through the Secretary, or officers, or employees of the Department, or to the courts."

That is very clear. All we would have to add is four little words—"or to the Congress."

We did that with respect to the section 7(c) and we could avoid a constitutional confrontation such as we face here. That is one remedy, to change the law which, after all, is the business we are supposed to be in, not putting people behind bars, not holding cabinet officers in contempt.

The second thing we could do is this; we have been furnished by the Secretary today with a list of the companies, the drug companies, which are involved. We have an opportunity to subpena this information and obtain it through those companies. Therefore, there are two different ways we have at our disposal today to avoid this particular confrontation.

I want to say that I have checked into this Michael J. Egan, who one of our members referred to as a clerk. He is not a clerk. He is the third ranking man in the Department of Justice under Attorney General Bell and Deputy Attorney General Civiletti. Then comes Mr. Egan. He is higher in rank than the Solicitor General of the United States, who comes below Mr. Egan.

Who the clerk was who write the Library of Congress study we are relying upon I do not know, but I have read both the Attorney General's letter and the Library of Congress study, and as a lawyer I can tell you that I would give an A–plus to the Egan letter and I would give a C–minus or perhaps a D–plus to the Library of Congress study which is a very inexpertly written and poorly drafted memorandum.

At this time I would be happy to yield to the gentleman from California.

Mr. WAXMAN. I assume the gentleman, as a lawyer, understands that ignorance of the law on the part of either the person charged or his

attorney is no excuse. I am of the firm opinion, I must admit I have looked into the legal precedents myself, that Congress is entitled to this information.

I see no distinction between this section 301(j) and the section to which former Secretary of Commerce Morton relied upon. I believe it is a way of the executive branch refusing to give Congress that information to which we are entitled in order to fulfill our obligations of oversight and legislation.

It seems to me that it makes no difference who the lawyer is. The question is really whether the advice is the kind of advice which ought to be taken.

My issue with the Secretary was that he was taking the advice of counsel where I think he can make a judgment for himself both as to whether he ought to conduct himself in accordance with the supena——

Mr. LENT. If I may claim the balance of my time, I would point out that I assume the gentleman is an attorney, though I am not sure of that fact, but he knows that there are two statutes—the confidentiality provision of 301(j) of the Food, Drug, and Cosmetic Act, and article 7(c) of the Export Administration Act, which are similar.

There is one important distinction. Section 7(c) contains one exception which stated if the Secretary determined it is in the natural interest to release the information he can. He ultimately made such a determination.

This Secretary who is before us today has no such right under 301(j). Congress in its wisdom made this confidentiality section absolutely airtight.

He has an opinion of the Attorney General, the chief law enforcement officer of the United States, adviser to the President and to the Cabinet, that he should not turn over this information. He is between a rock and a hard place. I hope he will stick to his guns. I intend to support and vote against the motion for contempt.

Mr. Moss. The Chair notes the time of the gentleman has expired.

I would say on the very day that we determined to cite former Secretary Rogers Morton we also had a meeting scheduled to consider contempt against former Secretary Mathews, of the Department of HEW, who was depending upon or relying upon a letter from the Attorney General of the United States dealing with title 42, section 1395, the Medicare Act, on the reports of the Joint Committee on Accreditation of Hospitals.

There was there an admonition to the Secretary to keep them confidential. It did not offer a subsequent disclosure to anyone. It said he should receive them and keep them confidential.

The Attorney General advised him not to give them to the committee. When faced with the certainty of the subcommittee considering the contempt citation, the Secretary, notwithstanding the advice of the Department of Justice, delivered the material to the committee.

Mr. LENT. If the gentleman would yield on one point.

Mr. Moss. Briefly.

Mr. LENT. Your recollection differs from mine. My recollection was that in the *Mathews* case there was a Attorney General Levi opinion which said he should turn the information over to the committee, and he did.

Mr. Moss. We will place the letters in the record at this point.

[The opinion referred to follows:]

OFFICE OF THE ATTORNEY GENERAL,
Washington, D.C., November 12, 1975.

Hon. F. DAVID MATHEWS,
Secretary, Department of Health, Education, and Welfare, Washington, D.C.

DEAR MR. SECRETARY: This is in response to your request of November 4, 1975, which I received on November 5, for my advice concerning your obligation to produce deficiency letters received from the Joint Commission on Accreditation of Hospitals (JCAH) to the House Committee on Interstate and Foreign Commerce. Shortly after receipt of your letter, we were advised that these documents have been subpoenaed by the Committee with a return date of 10:00 a.m., November 12, 1975.

I am sure you appreciate the difficulty of providing an opinion upon a complicated issue, whose incorrect resolution has such potentially serious consequences, within the space of a few days. We have, however, conducted as thorough an investigation of the matter as is feasible within the time available, on the basis of which we conclude that you should produce the requested documents.

As you may be aware, there is some question whether the documents requested even constitute "accreditation surveys" within the meaning of Section 1865(a) of the Social Security Act, 42 U.S.C. § 1395 bb(a). The position originally taken by your Department, and still suggested by its regulations, was that they did not. *See* 40 Fed. Reg. 27648, 27650 (July 1, 1975). That position was recently reversed by a stipulation entered into in connection with a suit brought by JCAH to enjoin the furnishing of these documents under the Freedom of Information Act, Civil Action No. 75 C 1751 (N.D. Ill., October 8, 1975). I find it unnecessary to consider this point, in view of my opinion on the issue of whether, assuming that the documents in question fall within the protection of Section 1865(a), that protection extends against requests from the Congress as well as against requests from the public at large. In my opinion, based upon the research we have been able to conduct within the short time available, it does not.

We have found no legislative history bearing upon the point. The language of the confidentiality provision, however, is as weak as can be imagined. It does not include, as many other statutes do, a general prohibition against disclosure (*see, e.g.*, 42 U.S.C. § 247c(e)(5)) but consists of the mere indication that material furnished to the Secretary may be furnished "on a confidential basis." Unlike an explicit prohibition against disclosure, this readily lends itself to the interpretation that information so furnished is not to be made public but may be conveyed to the Congress on proper request.

A second consideration which I find persuasive is the fact that the subject of this confidentiality provision is not material which is developed for the government, specifically in reliance upon a confidentiality assurance. To the contrary, JCAH accreditation surveys exist independently of any government reporting form or government information collection project. Thus, the only action taken in any conceivable reliance upon the confidentiality provision is the furnishing of this data, in its preexisting form, to HEW. It seems to me unlikely that that reliance included some belief that the information could be kept out of the hands of the Congress, since it was apparent upon the face of the statute, that Congress knew the existence of these documents and the identity of their sole possessor. It was obvious that the Congress could as easily subpoena the information from JCAH itself as from HEW. Or, to place the matter in its present context: It is apparent that if we now find, by reason of the statute, the Committee on Interstate and Foreign Commerce cannot obtain the information from HEW, they can immediately subpoena it from JCAH itself. There hardly seems any purpose to be served by such a circuitous procedure, and I think it would be unreasonable to assume that in enacting the vague and weak confidentiality provision of this statute, and referring specifically to JCAH, the Congress intended it.

The combination of the above discussed factors leads me to conclude that protection of JCAH accreditation surveys against congressional committee subpoenas is simply not a reasonable assessment of congressional intent. I will be happy to extend our investigation of this issue if you so desire, and to have the Assistant Attorney General, Office of Legal Counsel discuss it further with your General Counsel. If, however, you require my legal advice in time for your subpoena return date of 10:00 a.m. November 12, I must advise that you should produce the requested documents.

Sincerely,

EDWARD H. LEVI, *Attorney General.*

Mr. Moss. In any event, the chair wants to make it abundantly clear he is not relying upon the opinion of the Library of Congress for his position or his recommendations. He has read the opinion, and he has read the Egan opinion, and he has the same high regard for the Egan opinion that others would have were they free to express themselves on it.

At this time the chair recognizes the gentleman from Connecticut, Mr. Moffett.

Mr. MOFFETT. Thank you, Mr. Chairman.

Mr. Secretary, I woke up this morning and I thought Washington was bad enough on a hot August day without we Democrats having to bang heads with someone whom I regard as a fine member of the cabinet, perhaps the finest member of the cabinet, and perhaps the finest HEW Secretary in history, as well as a fine lawyer.

However, as I sit here and listen to the ground which has been covered very well by my colleagues, I am really very surprised that the Library of Congress opinion, when put next to the Egan opinion, if we might call it that, is not regarded by you and those around you as a far superior document and a far more compelling one.

In fact, looking at your work in the *Ashland* case and at this document by the Library of Congress, it is almost as though—if I did not know it was a Library of Congress document—you wrote the Library of Congress opinion which comes down on the side of many of us on the subcommittee who believe this information is important for us to have.

I assume you read the Library of Congress memorandum; is that correct?

Secretary CALIFANO. I have not personally read that memo.

Mr. MOFFETT. I would strongly recommend that it be read. I assume Mr. Libassi has read it?

Mr. LIBASSI. No; we have not yet seen that.

Mr. MOFFETT. This is an August 7 Library of Congress memo.

Mr. Chairman, if it is not already in the record I would ask now that it be inserted.

Mr. Moss. It has been included in the record.

Mr. MOFFETT. Thank you, Mr. Chairman.

Let me take a couple of moments to go over several of the highlights of this memo.

First of all, it was obviously in response to an inquiry by Chairman Moss.

Do you have a copy of it before you?

Secretary CALIFANO. Yes.

Mr. MOFFETT. On page 2 they first mention the express language which leaves little doubt that Congress does not intend to divest itself of its ability to gather information in this area.

On page 3 they go into some of the cases—*Watkins* v. *United States* in 1957, for example.

In the *Watkins* case, at the end of the citation, it states, "No inquiry is an end in itself; it must be related to, and in furtherance of, a legitimate task of the Congress." My colleagues made the point that our inquiry is a legitimate legislative one.

On page 4 they mention the *Eastland* case. There it states as follows: "This court has often noted that the power to investigate is inherent in the power to make laws because (a) legislative body can-

not legislate wisely or effectively in the absence of information respecting the conditions which the legislation is intended to affect or change."

Then they cite the *McGrain versus Daugherty* case, the 1927 case. There it is stated:

Experience has taught that mere requests for such information often are unavailing, and also that information which is volunteered is not always accurate or complete, as some means of compulsion are essential to obtain what is needed.

On page 5 of the memo it states:

Careful examination of 21 U.S.C. 331(j) reveals that neither its express language nor any necessary implication from that language restricts access by duly authorized committees of Congress to information held by the Department of HEW.

On pages 5, 6, and 7 they review instances where Congress explicitly limited itelf and strongly states that if we had wanted to do so with regard to this we would have done that. For examples, they state on page 7:

If the Secretary's construction of the provision is accepted, it would mean that over 100 similar confidentiality provisions could also be invoked by executive agencies against congressional requests for information.

The last paragraph on page 7 states:

It is difficult to accept such a construction on the face of this provision. Section 331(j) proscribes two types of activities. First, no one may use a trade secret lawfully obtained under the act for his own advantage. Second, no one may reveal trade secrets so obtained except to the Secretary or officers or employees of the Department or to the courts in a proper proceeding.

It would appear, then, that the Secretary and other officers of the agency are not prohibited by this provision from revealing such information if it is not to their "own advantage."

They continue on the next page as follows:

Thus, the limitation on disclosure, it may be plausibly argued, is aimed at the first level collectors of the information, a construction which is confirmed by the legislative history of the provision.

I would say to my colleague from New York, Mr. Lent, that the memo shows beyond any doubt that the intent of Congress is perfectly obvious to anyone who takes the time to study it.

They note near the end of the memo that executive agencies have numerous times raised several statutes of general applicability as barriers to the disclosure of information, important information, to congressional committees.

Much has been made of the Attorney General's opinion, the *Egan* opinion. I am not sure Mr. Egan read this excellent Library of Congress memo. I am disappointed that you did not have a chance to read it.

Let me ask this, and I am not trying to put you on the spot, but the subcommittee needs to know this—did you or any member of your staff, beyond your letter requesting this opinion, have discussions with the Justice Department about this matter?

Secretary CALIFANO. I cannot answer that.

Mr. LIBASSI. The only conversation I am personally aware of, Mr. Moffett, dealt only with the urgency of getting an opinion from the Department of Justice as promptly as possible. I did not have a discussion with them about the merits of the issue involved.

Mr. MOFFETT. Was anyone directed by you, Mr. Secretary, or by the General Counsel, directed to have conversations as to what HEW would prefer to see in the opinion from the Attorney General?

Mr. COOPER. At a very early stage, prior to the issuance of the subpena, when I first learned of this request for information and looked at section 301(j), I did have a telephone conversation with the Deputy Assistant Attroney General for the Office of Legal Counsel on the interpretation of section 301(j). That was one other additional contact.

Mr. MOFFETT. You did have a conversation?

Mr. COOPER. Yes.

Mr. MOSS. The time of the gentleman has expired.

The Chair wants to briefly put the record straight on the *Mathews* case.

On October 17, 1975, Secretary Mathews responded to the Chair stating that:

I have been advised by the General Counsel of this Department that it would be a violation of law for me to furnish you these JCAH documents given in confidence. I have enclosed a copy of that legal opinion for your information.

The legal opinion then is enclosed, and it would be made part of the record at this point, without objection.

[The material referred to follows:]

THE SECRETARY OF HEALTH, EDUCATION, AND WELFARE,
Washington, D.C., October 17, 1975.

Hon. JOHN E. MOSS,
Chairman, Oversight and Investigations Subcommittee,
House of Representatives, Washington, D.C.

DEAR MR. CHAIRMAN: This is in response to your letter of October 10 requesting three types of information under the control of the Department.

As you will recall, I visited your office recently to try to facilitate the exchange of information between our Department and your Committee. In that conversation I said that I wanted to give you a very thorough analysis of the utilization reviews as soon as it could be completed. It is the Department's intent to make that analysis as complete and accurate as possible, and for that reason, it was estimated that a certain amount of time would be required to do the job properly. I do not recall your voicing any objection to our projection that we could have this done by the end of the year. Rather, you seemed relieved that your early impressions that it was going to be drawn out over a long period were not borne out. That work is now well underway but, as you would expect, by no means complete.

Your recent requests seem to anticipate that process, and I am not quite sure I understand the purpose. I had presumed that after our last meeting we had agreed upon an orderly process that would meet common objectives.

Nonetheless, we are forwarding as you requested, "copies of all records, correspondence, memorandums, and documents anywhere within DHEW relating to the sufficiency of each state's [Utilization Control] showing since July 1, 1973".

We estimate that this request covers in excess of sixty thousand documents, most of which are in our ten regional offices. Collection and reproduction of these documents will require, in our estimate, thirty person-days and cost several thousand dollars. We have begun the copying of these documents, but it obviously will be impossible for us to produce all of them here in Washington by your deadline of 4:00 p.m. Friday, October 17. We are forwarding today under separate cover copies of those documents now available. The additional materials will be forwarded to you at the earliest possible time.

Second, your letter requests "copies of all drafts of proposed or final regulations, whether adopted or not, implementing Section 1512(b)(3) of Public Law 93-641 . . ." and "copies of all memorandums or correspondence discussing or commenting on the appropriate relationship between the parent board HSA and the health planning body".

We have now published in proposed form the Health Services Planning regulations, a copy of which I sent you with my letter of October 10. Before a regulation is complete, there are innumerable formal and informal position papers developed, some coming to the Secretary and some not. These papers are designed to present all options and to encourage diverse and differing opinions. They are in essence nothing more than the elements of a properly thorough and frank discussion, and their purpose is to produce a recommendation that has been exhaustively tested and carefully considered. Disclosure of that advice would result in the impairment of a free and open decisionmaking process. Disclosure would serve no useful purpose, but would, rather, have the effect of discouraging the professional staff from giving their candid advice and from elaborating on the diverse points of view which might be publicly sensitive. Therefore, in order to protect the integrity of the decision-making process, and in the interest of producing the soundest possible recommendations, I don't think I should provide working documents or option papers involved in the development of these regulations. I would urge you not to jeopardize an uninhibited deliberative process. I am under the impression that you follow the same principles as they pertain to your staff, and I would ask the same consideration for the staff of this Department. Moreover, by presenting the proposed regulation directly to you, you have full opportunity to review that regulation and pass judgment on it.

I have enclosed copies of all documents relating to the relationships between the governing board of an HSA and the HSA's governing board for health planning, except for documents from the professional staff which explore our policy options, for the reasons stated above. I did, however, forward to you with my letter of October 10 a copy of the General Counsel's opinion on the effect of the law on the colloquies since it was not merely opinion but a part of the decision reached.

Third, your letter requests copies of "statement-of-deficiences information which the JCAH has supplied to DHEW". As your letter indicates, section 1865(a)(2) of the Social Security Act provides for the release of hospital survey materials by the JCAH "to the Secretary (on a confidential basis)". I have been advised by the General Counsel of this Department that it would be a violation of the law for me to furnish you these JCAH documents given in confidence. I have enclosed a copy of that legal opinion for your information.

It is my desire to be responsive to Congressional requests for information. I also feel an obligation to protect the integrity of the decision-making process which I hope you will respect.

Sincerely,

DAVID MATHEWS,
Secretary.

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE,
OFFICE OF THE SECRETARY,
October 17, 1975.

To: The Secretary.
From: St. John Barrett, Acting General Counsel.
Subject: Medicare—Release to the Congress of JCAH deficiency letters.

Congressman Moss has requested that you release to him copies of "deficiency letters" sent to this Department by the Joint Commission on Accreditation of Hospitals (JCAH), and you have asked whether you must comply with that request. In our view the answer is no.

Section 1865(a) of the Social Security Act provides in pertinent part that (with certain exceptions) an institution will be deemed to meet the Medicare definition of a hospital if (1) the institution is accredited by the JCAH and (2) it authorizes the Commission—

> "to release to the Secretary (*on a confidential basis*) upon his request . . . a copy of the most current accreditation survey of such institution made by such Commission . . ." (emphasis added).

Prior to 1972, when this provision was added to the law, section 1865(a) had provided that JCAH accredited hospitals would be deemed to meet the Medicare definition, but had not provided any means for the Secretary to ascertain the basis on which JCAH had accredited the hospital (*i.e.*, he had no authority to obtain and review the JCAH survey forms). JCAH had consistently refused to release its survey forms to anyone other than the institution surveyed. The obvious intention of Congress in making this change in the law was to induce, by guaranteeing their confidentiality, the JCAH to provide its surveys to the

Secretary so that he would have the means to compare JCAH accreditation decisions with Medicare standards otherwise applicable.

In reliance on this Congressionally granted guarantee of confidentiality, JCAH has supplied the Social Security Administration with copies of letters to institutions that set out the deficiencies noted by the JCAH in its surveys (the so-called "deficiency letters"). JCAH has previously sued you to prevent the release of these letters to the public, and in that litigation we have agreed with JCAH that these letters are part of the "survey" protected from disclosure by section 1865(a).

Congressional committees have previously asked for release to them of these deficiency letters, and the Department has consistently refused to comply with those requests on the ground that the "confidential basis" phrase of section 1865(a) does not contain any exceptions for requests from other government officials, whether in the Legislative or Judicial branches, but rather is on its face an absolute pledge of confidentiality.

That interpretation obviously comports with the literal words of the statute. In addition, there is no legislative history indicating that the Congress intended any exceptions to be made to the general pledge of confidentiality. Anything less than absolute confidentiality would tend to defeat the purpose of the statute since JCAH is under no legal obligation to release any information to you and will presumably be most inclined to do so if it is assured of the maximum degree of confidentiality.

For these reasons we believe that refusal to release deficiency letters in response to Congressman Moss' request is consistent with your Congressionally-imposed obligation to maintain the confidentiality of JCAH surveys.

Mr. Moss. The opinion of the Attorney General coincidentally arrived the morning of the scheduled meeting of the committee, arrived just about the time the meeting was to be gaveled to order. It was 10 a.m., November 12, 1975.

At that point it followed by 1 day, I believe, the happening with Secretary Morton and the Attorney General's opinion had been changed.

The Secretary assured the chairman that he had also been advised by the Attorney General at the time of the October refusal to deliver the material to the committee. That is why we proceeded to move toward a contempt citation.

The Chair recognizes the gentleman from New Jersey, Mr. Rinaldo.

Mr. LENT. If I may, was it my understanding that the Attorney General's opinion will be in the record?

Mr. Moss. Indeed.

Mr. LENT. That states Mathews should turn over the information?

Mr. Moss. Yes; it said that to him the day after we had voted the contempt. I believe it was a day after or 2 days after the contempt citation against Mr. Rogers Morton.

Mr. LENT. I thank you for that clarification.

Mr. RINALDO. Mr. Secretary, it is good to have you here. I am sorry it is under these circumstances, because I believe I fully well understand the conflicting opinions in this case. I understand your desire to continue doing what I feel is an exceptionally good job.

As I understand it up to now, and I am sorry that I was a little late because I was involved in another committee meeting, what we are faced with are two conflicting legal opinions—the opinion of the Library of Congress which I have reviewed, which states you have to release the material, and the opinion——

Mr. Moss. If the gentleman would yield.

Mr. RINALDO. Yes, Mr. Chairman.

Mr. Moss. The Chair has made clear he is not relying upon the Library of Congress opinion.

We had it prepared as an informed third party.

We will, if the gentleman would like, have an opinion of the counsel of the committee. The Chair has heard that opinion, as well as the opinion of the Library of Congress.

I want the record to reflect that we are not relying upon the Library of Congress opinion except as an example of an excellent job of research and advice to the committee.

Mr. COLLINS. If the gentleman were to yield, I wonder whether we can have our counsel's opinion inserted.

Mr. MOSS. Yes; that will be done.

Without objection, it will be inserted at this point.

[The material was retained in subcommittee files.]

Mr. RINALDO. I understand the point the Chair has made. The Library of Congress opinion, in effect, states that the material should be released.

On the other hand, the Secretary has been advised, if I understand it correctly, by the Department of Justice that he is, in effect, prohibited from releasing the material.

Mr. Secretary, what would you do if a court ordered you to comply?

Secretary CALIFANO. If the court interpreted that statute, I would obey the order of the court. That is the way the system of Government works.

Mr. RINALDO. Let me pose this to you, then:

If Congress were willing to waive its immunity to suit, would you be willing to bring an action for a declaratory judgment and have a court decide this issue?

This, in effect, would allow you as the Secretary to sue Congress to contest the contempt citation. It negates the need for a criminal proceeding.

I think this is one way of resolving the problem, because what it really boils down to is a dispute between two separate branches of Government.

Secretary CALIFANO. It is a difference between myself as Secretary and an ordinary lawyer-client situation.

It is not within my power to decide whether or not or when we can go to court. That is up to the Attorney General of the United States. I have no control over that.

Mr. MOSS. We are in the same position as a committee of the Congress. Any such action would require a resolution by the House of Representatives authorizing such action.

Mr. RINALDO. The reason I bring it up is because I am trying to find some way of avoiding a confrontation which, obviously, faces us.

I would think we can work out, if both sides were reasonable, this type of proceeding perhaps, having a privileged resolution brought before the House, and then ask the Secretary to discuss the matter to see whether he could obtain permission to bring suit through the Department of Justice.

Mr. MOSS. In the opinion of the Chair, such a resolution would not be a matter of high privilege.

Mr. RINALDO. Would not the resolution be privileged in dealing with the prerogatives of the House?

Mr. MOSS. You are aking for permission for us to intervene in a case and to authorize employment of counsel for that purpose.

Mr. RINALDO. What I am asking is that we would have to waive our immunity.

Mr. Moss. Only the House can waive our immunity.

Mr. RINALDO. That is exactly the point.

Then, if the Secretary received an agreement to bring the suit, the confrontation would be avoided. The court would decide the case. I guess the matter would rest at that point.

I cannot think of any other friendly way of working out this conflict.

Mr. Moss. I would say that the gentleman is suggesting that we abandon the inquiry for the balance of this session of the Congress and leave it for the 96th Congress to determine, whether this question regarding the excess costs of certain drugs be addressed by them rather than by us.

There is no way we can do what you are asking——

Mr. RINALDO. Not at all. We can obtain prompt action from the courts. You still have a criminal proceeding.

Mr. Moss. I was contemplating prompt action. That is why I said it could not be done during this session of Congress.

Mr. RINALDO. For the record, I would like to see whether the Secretary would be agreeable to such a possible method of resolving this problem.

Secretary CALIFANO. As I said, it is not for me to decide. That is a question you have to direct to the Attorney General. He is the only one with power to bring a lawsuit. I do not have the power to bring a lawsuit.

Mr. RINALDO. I recognize that fact. Would you be willing to discuss this method of resolving the problem with the Attorney General?

Secretary CALIFANO. Let me think about it. I do not want to be my own lawyer here. I am by no means certain that this is a situation where you can get a court to take a declaratory judgment route.

Second, as far as the chairman's comment is concerned, I don't think there is any way you can get a resolution of this type under the circumstances in less than a year or two.

Mr. MARKS. Mr. Secretary, have you requested of Mr. Libassi an opinion on this problem and have you given an opinion to the Secretary, Mr. Libassi, and do you agree with the opinion given by the Attorney General?

Secretary CALIFANO. Let me say, Mr. Marks, that I have not asked Mr. Libassi for an opinion.

We asked the Attorney General for an opinion on an interpretation of this.

I have no objection to submitting to the Attorney General the Library of Congress memorandum, which we saw for the first time this morning, and getting the Attorney General's view of that memorandum to see whether or not it has any impact on the opinion of the Attorney General.

We would be happy to do that if the committee would like that.

Mr. MAGUIRE. I wonder whether this committee ought not to call the Attorney General.

Mr. Moss. The time of the gentleman has expired.

The Chair points out that his advice to the committee is that he would be very reluctant to comply with an order of the committee to

call the Attorney General, in view of the fact that we do not have legislative jurisdiction over the Attorney General.

We might find ourselves in a position where we can suffer some embarrassment.

The Chair recognizes the gentleman from Nevada, Mr. Santini.

Mr. SANTINI. Thank you, Mr. Chairman.

Mr. Secretary, it is pleasant to share this morning with you. Hopefully, it could have been under different circumstances.

This is one of the most curious paradoxes this member has witnessed in a town that lives from day to day with paradoxes.

On the one hand we have my good friend from Texas, a long-standing battler of the bureaucracy, urging the leader of one of the Nation's largest bureaucracies to maintain your independent fighting spirit.

On the other hand, we have a very able lawyer and member of this subcommittee from New York giving the democratic Attorney General a grade of A or A-plus.

It does seem to me that some of the dialog which has been exchanged in the form of questions and answers or rhetoric has been played before. It has been played on a very fundamental issue of Congress right to know.

As you appreciate, Mr. Secretary, the chairman of this committee is perhaps the champion of that interest in that pursuit. I share with him this fundamental commitment and enthusiasm about clarifying entitlement of Congress with regard to acquisition of information or evidence from the executive branch.

I think, as the gentleman from Connecticut observed, the Library of Congress opinion concludes our power to legislate and investigate is inherent. If it is impeded, constrained, inhibited, we are that much less able to legislate.

Solutions have been proposed, well-meaning and well-intentioned solutions, in the pursuit of trying to reconcile this issue.

One was a suggestion of changing the law. Every time we ask for information from a governmental agency if in that circumstance we got the rejoinder that, "We don't think we can give it to you," and we were compelled to change the law, as the chairman observed earlier, we would have 100 laws we would have to go about changing.

We are already seriously backlogged in our legislative hurdles. Changing a law every time we need evidence is not a rational or practical solution or approach.

Mr. Marks suggested, and in all sincerity, the subpena route.

Not only is it suggested that it would be a year and a half of endeavor to secure the subpenas and obtain the information, but it seems that that too is flawed.

Any one of those subpenas can be challenged by injunctive relief in Federal district court.

If that avenue is pursued, the entire investigative process then finds itself stalemated, at least for the duration.

Unlike some other members of the subcommittee, I do not shirk from a constructive confrontation with you, Mr. Secretary, or any other Government agency to try to arrive at some judicial resolution of this fundamental question of our ambit of entitlement to obtain information from the Executive.

We are up against this sort of thing time and time again in critical investigative pursuits.

Whether Republican or Democrat, in all sincerity, they do not have the legal authority to turn over that information and we are stalemated again.

Do you see a legal feasibility or a practical way of perhaps short-circuiting some of the objections and concerns by your stating an intent to turn over this particular information as of a designated time?

The virtue of that course, it seems to me, is immediately the concern of the drug companies. They would then have an option.

If they feel there is some jeopardy attached to the disclosure of that information, they then can immediately implement it and they become the implementers of the legal course of action. They could go to district court and seek an injunction based on section 301(j) or other legal precedents they may want to use.

Then we would find this in the context of a friendlier legal determination of exactly what is the scope of Congress right to know and hopefully would get some substantial judicial clarification of our role, your role, and the entire issue of Congress right to know.

Secretary CALIFANO. One, I do not think a cabinet officer or anybody who is an official in Government in the context of the Attorney General's opinion can state an intention to commit a crime, which would be what I was stating.

Second, the lawsuit gets complicated for the drug companies while the issue of whether or not you can use a criminal statute to protect a noncriminal civil right and in effect enjoin a possible commission of a crime in the future.

A lawsuit would become entangled with procedural problems, as well as substantive problems.

I am not my own lawyer here, and I do not want to get into these issues.

Mr. SANTINI. Most of the members of the committee are pursuing alternative courses of action which would insure that you, in the extreme, did not end up sharing a jail cell with cigarette smokers and other nefarious sorts.

Mr. MOSS. I think we would try to get him a hotel room.

Mr. SANTINI. But as we probe these alternative courses, it does seem we are coming down to a constructive collision course.

There is no malice involved as you sit there in the cell looking out the window—nothing personal, as the expression goes.

But in our effort to try to get some clear delineation of where we are as the prime investigatory arm of the U.S. House of Representatives, every time we seek to probe these murky waters with statutory interpretation and conflicting opinions—and I am not anxious that you inspect the interior of the local hoosegow—but it seems that is the only way of coming down on these things.

I would like to try, in the context of a friendly lawsuit, to pursue alternative solutions.

Secretary CALIFANO. I do not think I would ever be able to explain to my mother what I was doing in jail.

Mr. MOSS. The time of the gentleman has expired.

The Chair recognizes the gentleman from Pennsylvania, Mr. Walgren.

Mr. WALGREN. I would like to pursue the problems created by going that very direct route toward the companies who have a clear obliga-

tion to yield this information, and, facing a conflict of interest, I find myself very reluctant to rush to the constitutional confrontation.

For one, the use of the contempt power by the committee is one I would be extremely reluctant to see us use—if only because I was brought up at an age where some of the lowest points of congressional activity were involved in the use of the contempt power, far too broadly in my opinion, and it trampled on the rights of many individuals.

Not that this committee would trample on the rights of Mr. Califano, but I feel that the contempt power is something that should be approached solely as a last resort.

The other thought wtih regard to the contempt power is that we talk of ignorance of the law being no excuse. However, when you find a person in contempt, I would think that hopefully that person would not have a sincere conflict of interest or a sincere conflict that he faces some kind of Hobson's choice but it is a personal choice of that person to violate the real spirit of his obligation.

I think here, where the Secretary is not even presented with the legal document that is so convincing from the congressional point of view as to the legislative intent, that he certainly is not in that position at this point.

We tend to shy away, I gather, from pursuing the companies because of the time delay which the companies could impose on us by going to court to prevent the implementation of an injunction or our recourse against them.

How long would it actually take? Some judges can be very direct. I am not at all convinced we are faced with that problem.

Mr. Moss. The Chair's recommendation to this committee is really not based on the time constraints. The Chair feels very deeply, as a result of many years of chairing investigative committees, that unless the Congress is willing to assert its rights when those rights are challenged, they will surely be eroded to the point where we have no rights.

I have seen occasions where we have come perilously close to that.

I do not think we can permit the executive department to determine what we can look into.

The executive department can be guilty of the grossest mismanagement of the Federal establishment, and we have a right to look at it and determine that.

After all, there are only two persons in the executive department who are ever subjected to the franchise of the American people—the President and the Vice President.

Every Member of this House is subjected regularly to a review by the people, and every Member is accountable to the people.

With all due deference, that is not true as regards the Secretary. He has a constituency of precisely one, the President of the United States.

You have a constituency in excess of a half million people. Your responsibility to see that this Government works properly and achieves a balance is greater than that of the Secretary.

I would charge every Member of this House with being mindful of the nature of representative government, of the kind of burden you assume, and of the responsibility you have when you leave this office,

as I am now leaving it, to be certain that no action of yours has in any way diminished the grandeur of the system of representative government.

We are close to that when we permit a department to come up here and say, "you cannot look at this," and they take an obscure statute and also say, "this is the barrier. If you don't like it, go to the other branch of government and litigate. We can frustrate you forever in the courts."

That is the kind of thing we are seeing here today. I urge very strongly that my colleagues not permit that to happen.

Remember that in this instance you may feel that to protect this kind of information is desirable. However, there are over 100 statutes and that is a loose compilation because it may be closer to 150 or 200, covering every kind of activity of the American people, and that can be raised.

We take the basic statute dealing with trade secrets. It has been construed by the courts as not being binding on the Congress. But, nevertheless, if you read it, it is as clear as this one, that it can be so construed by an overly zealous administrator. It is but one of the many that can be relied upon.

You must meet the challenge when it is raised and becomes an obstacle in the course of doing your job.

I thank the gentleman for yielding.

Mr. WALGREN. If I might just complete my thought.

My own view is that certainly, before the Congress would use the contempt power——

Mr. Moss. If I may interrupt further.

Mr. WALGREN. Certainly.

Mr. Moss. May I state that the Secretary has an appointment which has been scheduled for some time. It is the opinion of the Chair that if he can return to a couple questions of the Secretary that we can then accommodate him to keep his appointment.

Mr. WALGREN. I would be happy to yield.

Mr. Moss. Mr. Secretary, you have heard a rather extensive discussion here.

As I think you recognize, there is a depth of feeling some of us have over the situation confronting us.

You also recognize very fully the position of those of us who feel that you have really no alternative but to comply with this subpena.

In view of that, do you still refuse to respond to that subpena with the full information sought by this subcommittee in the issuance of the subpena?

Secretary CALIFANO. Mr. Chairman, I feel that I have no choice but to comply and follow the opinion of the Attorney General. Therefore, I cannot provide trade secret information relating to manufacturing processes.

I would like to underline the point that it has nothing to do with my judgment of the desirability or undesirability of providing that information.

It has nothing to do with any judgment of the right of Congress to have it or not to have it, or the ability of this committee which has such a distinguished record to protect that information and to keep it confidential.

It is simply following an opinion of the highest legal officer of the executive branch, the Attorney General, and his interpretation of the statute.

Mr. Moss. Mr. Secretary, I now order and direct that you supply the material to the committee. Will you do so?

Secretary CALIFANO. Mr. Chairman, as I indicated, I cannot supply that particular material to the committee under the ruling of the Attorney General.

Mr. Moss. Mr. Secretary, it is the opinion of the Chair that you are now in contempt of this committee and of the House.

Under the rules of the House, the Chair will propose to his colleagues the steps necessary to bring about the further action by the committee and by the House on the matter of contempt.

Now, Mr. Secretary, we will attempt to accommodate your request. You are excused at this time.

Mr. GORE. Mr. Chairman, I have a resolution.

Mr. Moss. The clerk will report the resolution.

The CLERK. Resolved that:

One: The subcommittee finds Joseph A. Califano, Jr., in contempt for failure to comply with subpena No. 95–2–75 issued by the subcommittee on August 4, 1978; and

Two: The facts of this failure be reported by the Chairman of the Subcommittee on Oversight and Investigations to the Committee on Interstate and Foreign Commerce for such action as that committee deems appropriate.

Mr. Moss. Is there discussion?

Mr. GORE. It is with reluctance that I offer this resolution, but it comes from my opinion that this subcommittee must pursue the rights of the Congress.

The information we are seeking from the Secretary is essential to a proper fulfillment of our duties of oversight and investigation, in our responsibility to the Congress as a whole to make recommendations about changes in the current laws.

I have great respect for the Secretary as an individual. I believe the advice he has been given by the Attorney General is misguided and mistaken.

Beyond that, the right of the Congress, pursuant to Article I of the Constitution, compels this subcommittee to press its right to see the information we have requested from the Secretary.

I ask my colleagues to support the resolution.

Mr. Moss. Is there further discussion?

Mr. COLLINS. In the event that we do support this resolution, will the Secretary have to appear before the full committee or will the hearings be completed that day?

Mr. Moss. That will be up to the full committee.

As you know, the Chair manages only on behalf of the subcommittee the business of the subcommittee. It is up to the chairman of the full committee.

I would think, ordinarily, however, the Chair having gone through a number of contempt cases in the past, that the matter would be called up in the full committee and thoroughly debated, but there would not be an additional witness.

Mr. COLLINS. I would hope that the committee, in its judgment, will not vote out this resolution.

We have had in our hearings today many alternatives as to how the questions, the issues, and the information we desire can be gotten.

My colleague from Pennsylaniva suggested many alternatives.

To have a confrontation where all we are trying to do is to prove to the world, and I guess to ourselves, that Congress has power over the executive department, is a tremendous mistake in the governmental process of the United States. I think it would be a serious mistake.

Mr. Moss. If the gentleman would yield.

All we are trying to prove is not that Congress has power over but the inverse—that the Executive does not have the power over the legislative branch.

Mr. Marks. Mr. Chairman, I feel compelled to say that I am very concerned about this issue. I find that we have the Secretary in the horns of a dilemma. That dilemma, to some extent at least, is set in motion by an opinion of the Attorney General.

I do not know that there is any reason this resolution needs to be voted on immediately.

It is my thought that at the very least we ought to give it a day or so before we vote on that resolution and consider, if nothing else, bringing the Attorney General of the United States before us.

In the meantime, there may be some other method that can be used to prevent the necessity of this confrontation coming about.

Mr. Gore. We first requested this information on July 11. I think we have given them sufficient time. There have been lengthy negotiations in private before this scenario ever took place.

It was only when the subcommittee came to absolute loggerheads with the executive branch that this action was even contemplated. I think we have waited too long already.

As to the gentleman's second point, I believe these may be some merit to it, but I personally think it would be unseemly for us to have the Attorney General here and question him about the advice that he has given another member of the Cabinet.

I feel that is for the executive branch to work out on its own. It is for us to press our rights and responsibilities as a legislative branch of this Government.

Mr. Marks. It is my thought that one of the major problems we have here, not only in this committee and not necessarily in this committee but in the Congress, is a lack of communication.

I suggest to you that the better part of valor at this point would be to wait until at least the first of the week before this resolution is voted on and see whether or not, by intervention of certain members of this committee, this matter can in some way justly be worked out.

I am also concerned about the prerogatives of this Congress, and I feel very strongly about them.

Mr. Moss. The Chair will point out that tomorrow evening this House goes into a recess until September 6. Therefore, a vote would not be possible.

More importantly, we had movement forward toward a resolution of the problem of confrontation with Secretary Morton only after voting contempt and scheduling it as a matter of privileged business before the full committee.

I assure the gentleman that the Chair will, in good faith, as he has acted in good faith before, attempt to resolve this matter. He has had

the difficulty of dealing with the Department in an effort to resolve something while at that time the Department was getting a position from the Department of Justice.

The Chair must say that for a significant period of time urging of that position was not disclosed to him by the Department.

In any event, we have tried to work in good faith with the Department to bring about an accommodation. I do not think this is a confrontation that is promiscuously approached by any member. We are most concerned about the nature of it.

Mr. LENT. I am similarly concerned about the prerogatives of Congress and believe there should not be any obstruction to the ability of this body to get the information it needs in order to conduct its investigations and in order to legislate.

However, I also feel very strongly that the contempt procedure should be adopted only as the very last resort of this body; and it ought to be adopted only when there is no other method by which this information, or the desired information, can be obtained.

We have already heard today three suggestions, alternate suggestions, for obtaining this information:

No. 1, the statute could be changed.

No. 2, we have been provided by the Secretary with a list of the companies which are involved, and we have the ability to subpena the information from those companies directly without admonition of the statute being in the way.

We also have the suggestion made by the distinguished member from New Jersey that Congress could waive its immunity and a declaratory judgment could be instituted to determine the validity or determine the effect of this statute, section 301(j), with respect to the Secretary's turning over the confidential information.

In view of the fact that we have these three other possible alternative modes of action which would avoid what is, in effect, a constitutional confrontation, I am going to make the privileged motion that the matter be tabled.

Mr. Moss. The vote occurs on the motion of the gentleman from New York, and a rollcall is requested.

As many as favor a vote by rollcall, will signifiy by raising your hands.

[Show of hands.]

Mr. Moss. Obviously, there is a sufficient number.

A rollcall is ordered.

The CLERK. Mr. Santini?

Mr. SANTINI. No.

The CLERK. Mr. Luken?

[No response.]

The CLERK. Mr. Walgren?

Mr. WALGREN. Aye.

The CLERK. Mr. Gore?

Mr. GORE. No.

The CLERK. Mr. Carney?

[No response.]

The CLERK. Mr. Waxman?

Mr. WAXMAN. No.

The CLERK. Mr. Sharp?

[No response.]
The CLERK. Mr. Moffett?
Mr. MOFFETT. No.
The CLERK. Mr. Maguire?
Mr. MAGUIRE. No.
The CLERK. Mr. Krueger?
[No response.]
The CLERK. Mr. Collins?
Mr. COLLINS. Aye.
The CLERK. Mr. Lent?
Mr. LENT. Aye.
The CLERK. Mr. Rinaldo?
Mr. RINALDO. Aye.
The CLERK. Mr. Stockman?
[No response.]
The CLERK. Mr. Marks?
Mr. MARKS. Aye.
The CLERK. Mr. Moss?
Mr. Moss. No.
The CLERK. Mr. Chairman, I have two proxies for Mr. Collins—those of Mr. Devine and Mr. Stockman.
Mr. COLLINS. Mr. Devine and Mr. Stockman vote aye, by proxy.
The CLERK. Mr. Chairman, I have a proxy from Mr. Luken for Mr. Walgren.
Mr. WALGREN. I do not know how he would vote. Therefore, I cannot vote his proxy.
The CLERK.Mr. Chairman, the vote is seven ayes and six nays.
Mr. WAXMAN. Mr. Chairman, before the vote is announced, might I make a parliamentary inquiry?
Mr. Moss. Yes.
Mr. WAXMAN. Is there an opportunity for a member to change his vote before the vote is announced?
Mr. Moss. Yes; there is.
Mr. WAXMAN. If one votes on the prevailing side, is there an opportunity for that member to then move for reconsideration?
Mr. Moss. There is an opportunity to move for reconsideration.
Mr. WAXMAN. I request that my vote be changed from no to aye.
Mr. Moss. Does anyone else desire to change his vote?
[No response.]
Mr. Moss. The Clerk will announce the vote.
The CLERK. Mr. Chairman, the vote is eight ayes and five nays.
Mr. Moss. Let the Chair make very clear what is happening.
The vote is eight ayes and five nays.
The committee has now abandoned the investigation for the balance of this Congress. The Department has succeeded in its desire to have the effective inquiry into the excess pricing of name-brand drugs frustrated because there is no means available to us to secure the information we want within the life of the 95th Congress.
I hope that the members will fully appreciate that. There is also nothing to negotiate with the Department because the committee has indicated it is supportive of the secondary role of the Congress to the executive. It is a very dangerous precedent you gentleman have adopted.

I congratulate you on it.

Mr. GORE. Mr. Chairman?

Mr. MOSS. Mr. Gore.

Mr. GORE. In light of the fact that we have a quorum call on the House floor, I would like to register my presence there.

I would request that we take a 15-minute recess.

Mr. MOSS. The Chair has no alternative but to grant the recess. We will come right back.

The Chair strongly suggests the need to get the other three items on the agenda disposed of.

[Recess taken.]

Mr. MOSS. The subcommittee will be in order.

Gentlemen, this is a continuation of the meeting of the subcommittee started earlier today.

We had disposed of the matter of Mr. Califano, Secretary of HEW.

What is the desire of the committee at this time? We have three resolutions before us.

Mr. WAXMAN. Mr. Chairman, before we undertake consideration of new material before the committee, I make a motion that we reconsider the last vote, whereby the contempt citation issue was tabled.

Mr. MOSS. The gentleman is recognized for 5 minutes on his motion to reconsider.

Mr. WAXMAN. I made this motion, having voted on the prevailing side, solely for the purpose of offering the members of this subcommittee the opportunity to register their votes on what I think is an important constitutional question.

The issue before the subcommittee is the right of Congress to know. Will we be allowed to get the information that I think we are entitled to have by virtue of the Constitution—information which will enable us to carry out our responsibilities in legislation and in oversight?

We are talking about the issue of whether the public and the taxpayers are being ripped off by brand name drug manufacturers who are not offering drugs which justify sometimes two and three times the price of generic substitutes.

For us to determine that, is seems to me we must have the information we requested from the executive branch.

If the Secretary of HEW, whether he be a Democrat or a Republican, refuses to give Congress that information, I see we have no other recourse but to assert our constitutional rights and privileges.

Therefore, I would ask that the motion which was successful about 45 minutes ago, to table the whole issue, be reconsidered and, if we are successful in reconsidering that motion, we be permitted to address the issue of contempt.

Mr. MAGUIRE. I thank the gentleman.

I concur entirely with the gentleman. I also think it is extremely regrettable that we are at this point. The fact of the matter is, however, that we are at this point. The motion to table was made after the suggestion that there might be some circuitous way that this committee should attempt to conduct its business.

The notion that we ought to change this act and perhaps hundreds of other laws in order to obtain information, the notion that we might have recourse to the courts for some sort of declaratory judgment, the notion that we can compel the companies to supply the information—

all these options miss the essential point which the gentleman from California has so clearly stated. The point is that this committee be unable to pursue its investigatory role unhampered and will not have access to the information that it needs in order to fulfill its role and function.

I, therefore, join with the gentleman from California in urging that the motion to table be defeated.

Mr. Moss. Is there further discussion?

The Chair first would like to state the motion on the motion that we reconsider the vote whereby the resolution of contempt was rejected earlier by the subcommittee.

The Chair recognizes the gentleman from Pennsylvania, Mr. Marks.

Mr. Marks. I do not agree with the statements made by my colleagues. I do not think that is the issue at all.

The issue, as I saw it at the time of the previous vote, was whether or not it is advisable under the circumstances, with the serious questions, constitutional and otherwise, we might have before us, to at least delay action upon Mr. Gore's resolution for a reasonable period of time.

As the chairman pointed out, we are going into a recess. That would mean 10 days or 2 weeks. I understand that.

However, it seems to me it is not an unreasonable period of time, considering the problem facing us.

It is for that reason that I voted as I did, and I believe I will continue to vote as I did previously.

We have had some discussion as to other methods. But, be that as it may, I am as concerned as anyone else about the right of Congress to get information we should have. I am very much in favor of that.

However, I think under these circumstances, it is incumbent upon us to do whatever we can, including perhaps bringing the Attorney General before us, before we take the very drastic step which is called for by Mr. Gore's resolution to hold Mr. Califano in contempt.

Thank you, Mr. Chairman.

Mr. Santini. If I might address the issue, No. 1, of delay.

It seems to me that July 11 to the present date is certainly a reasonable time interval with which this matter could have been reconciled.

I am further persuaded, and I hope the gentleman from Pennsylvania will share this persuasion with me, that the passage of this resolution from the subcommittee to the full committee will encompass the 2 weeks the gentleman envisions, and perhaps another week as well.

I think this resolution will provide added impetus to a responsible reconciliation which the gentleman seeks.

I think to leave this matter in abeyance without any kind of momentum or impetus to support it will merely insure that the status quo confrontation continues without any realistic hope of resolution.

Mr. Marks. If the gentleman would yield for a moment.

Might I suggest that you may well be right. On the other hand, I am not sure you will be, and because of the lack of additional communication and other reasons we might be doing a disservice to ourselves and to the Secretary.

My thought is that a 2-week delay at this particular point would not cause a problem. If, in fact, we had not secured at the end of that period of time enough information to satisfy us in a fashion

that is not called for, holding the Secretary in contempt, I would vote at the end of that period of time on the contempt citation affirmatively.

Mr. SANTINI. I appreciate the gentleman's sincere intent. I think in practical assessment, however, that there will be just more time lost than problem resolving here. I would think that decisive action by the subcommittee is going to give the time we need to get to the basic problem.

Two fundamental issues are posed—one, the right of Congress to know; the other, the merits of the investigation.

I think both are impeded if we let this thing drag out, do nothing, have inaction for 2 or 3 weeks.

The three alternatives posed are no alternatives that can be rationally pursued in this Congress. The gentleman from New Jersey suggested declarative judgment.

We attempted that course of action 2 years ago and were advised by the Library of Congress in the legal opinion we sought that a declarative judgment would not in all probability be well-received by the courts because there was not a case of controversy which would invite the courts for consideration.

Mr. RINALDO. If you would yield on that point.

I proposed the same course of action with regard to Secretary Rogers Morton, as you ably stated.

However, the Library of Congress opinion was the only opinion that I believe we received at that time. I disagreed with the opinion.

There is a difference in this case. The argument against seeking a declaratory judgment in the Morton case was the argument of ripeness. This case is ripe because Secretary Califano faces criminal charges.

There is a difference, then, which would cause perhaps even the Library of Congress to change its legal opinion on this particular matter.

I think that the gentleman, being an able attorney, recognizes that fact.

Mr. SANTINI. Reclaiming my time, and for whatever legal judgment I can bring to bear on the issue, I am substantially persuaded that the issue is at best murky, confused, and unresolved.

To try to use that as a solution in the context of this resolution suggests to me a 2- or 3-year delay in court, a delay in construction and reconstruction. This would not be desirable.

The proposal to rewrite the laws is one that I think inherently must be rejected as totally impractical in the context of 30 days or less of legislative process left, and a solution that will guarantee inaction and nonresponse.

I am very much persuaded at this point that the only way we will bring this matter to a head in terms of both the substantive issue and Congress right to know is to allow this subcommittee to pursue the course of action proposed by the chairman, and that is to let the resolution proceed to the full committee for full committee discussion and examination and for further review of the question that my good friends on the minority have posed.

I think in the interim that we will get a reconciliation. I think by inaction I could guarantee we will not have any decisive course pursued as long as we remain in that state of abeyance or inaction.

Mr. MARKS. If I might take this opportunity to mention to the gentleman, whom I respect very much, whose opinion I very much respect, as I understand the testimony today neither the Secretary nor his counsel have either had or taken the opportunity of reading the legal brief, so to speak, which we received and to some degree on which we have relied.

It seems to me we need not be any more stringent in our position or straightforward in our position than at the moment. The Secretary has reason to believe that within a short period of time very drastic action will be taken.

I suggest those 10 days or 2 weeks, if for no other reason than for him to involve himself more deeply in the legal presentation we have had.

Mr. Moss. The Chair hopes that having had almost 3 hours of extended discussion the members can conclude and are prepared to act without yet another hour or two of discussion.

Mr. LENT. As the author of the motion under attack, I would hope I would be recognized.

Mr. Moss. The Chair will not cut anyone off. He is expressing a hope. He also wants to make another point.

The Chair stated he was not relying upon the Library of Congress opinion solely. However, I do not think there is a point in the Library of Congress opinion which has not been argued extensively, thoroughly, and exhaustively with the Department of Health, Education, and Welfare during the past approximately 3 weeks.

Therefore, while the opinion in its present form has not been formally before the Secretary or his counsel, the substance of it has been very much before him and has been discussed, as I stated, endlessly.

Mr. WAXMAN. I would like to address the point raised about keeping this issue going and considering it at a future time, as Mr. Marks suggested very convincingly.

I would suggest that we adopt the motion to reconsider, which would have the matter before the committee, and remove it from the table on which it was placed.

Then I would agree with Mr. Marks that the subcommittee ought to consider waiting until our return from the Labor Day recess so that the Secretary of HEW might further review the legal opinions which were furnished him today, and that negotiations proceed so that perhaps a compromise can be worked out.

I don't think if we leave this matter tabled, we can procedurally get it back on our agenda.

Mr. Moss. If the gentleman would yield.

I would hope you would make no such commitment.

The Chair tells you from a practical standpoint that if we followed the course of action being recommended, that there is not a chance of a snowball in Hell for this subcommittee to get the facts and get them examined before this Congress adjourns.

There may be one or two members here who know for certain they will be Members of the 96th Congress. I know I will not be, by my own choice.

Nevertheless, for all practical purposes this totally aborts the investigation, either course.

Mr. WAXMAN. I was making the suggestion as a practical concern and not that my mind is convinced we ought to pursue and assert our constitutional rights and privileges. I was concerned that perhaps the members of this subcommittee might not be willing at the present time to have the matter still before us.

If the Chairman wishes us to dispose of it today and feels the only way we can handle it is to dispose of it today, I am willing and prepared to vote to hold the Secretary of HEW, a man from my own party and a man I respect greatly, in contempt of the Congress.

I was suggesting as a practical matter that any move to delay the issue might well follow a successful motion for reconsideration.

What is before us now is solely a motion for reconsideration so that the whole issue will not be tabled indefinitely.

Mr. Moss. Is there further discussion?

Mr. Lent.

Mr. LENT. Thank you, Mr. Chairman.

The gentleman from California said earlier that the only issue before us was the issue of Congress right to know. I respectfully disagree with the gentleman. I think that the issue here is whether we are going to obey the rule of law or whether we are going to obey the rule of expediency.

Certainly it would be more expedient to hold the Secretary in contempt in an effort to get the information through that route.

Just as we have learned over the past 5 or 8 years, that the President is not above the law, that the FBI is not above the law, that the CIA is not above the law, certainly today we are voting on the question of whether Congress is to be above the law or whether we are going to vote to obey the laws that we enacted. That is the issue as I see it.

We have a statute on the books which our predecessors, in their wisdom, wrote and put on the books, saying in no uncertain terms that there is a rule of confidentiality and that the Secretary would be guilty of a violation of that law should he divulge the information that he has in his possession.

He is fortified by a ruling of the chief law enforcement officer of the United States to the effect that it would be a violation of the law.

I do not feel very comfortable, Mr. Chairman, urging the Secretary to violate a statute of the United States I think that Congress has to operate. We have a right to know, certainly, but within the law—within the law. It is very important that we establish that precedent that we are going to operate within the law.

I think, Mr. Chairman, everyone has had an opportunity to discuss this, and I would like to move the previous question.

Mr. GORE. If the gentleman would withhold as a maker of the motion.

Mr. Moss. Let the Chair observe first that the gentleman moved promptly to cut off debate as soon as he had his say of giving misinformation to the committee.

This is not a question of whether or not we are going to obey the law. It is a question of whether we are going to blindly accept——

Mr. LENT. Point of order, Mr. Chairman.

Mr. Moss [continuing]. Accept the ruling of the Attorney General which is not binding on the Congress.

Mr. LENT. Point of order, Mr. Chairman.

Is it not correct that a motion to move the previous question is not debatable?

Mr. Moss. The Chair will put the motion when the Chair is prepared, Mr. Lent. He has the right and the responsibility to at least comment in order to correct the record.

I pointed out we are not faced here with the judgment of the court or the Almighty God but faced with a badly drafted opinion of an Assistant Attorney General—not the chief law enforcement officer of the United States but, as I put it, the third-ranking man in that office. He is acting in this instance only as the chief attorney for the executive branch of the Government of the United States, the Congress being a significant part of the Government of the United States.

The question occurs on the previous question.

Mr. Gore. As the maker of the motion which he moved to table, if he would withhold, I would like to speak to it.

Mr. Lent. I will withhold for 2 additional minutes.

Mr. Gore. I appreciate that very much, because I genuinely believe we have some members of the subcommittee who are undecided. I think they are genuinely wrestling with the great constitutional issues involved in the question we are facing here today.

Congress has a right to information. It is implicit in our duty to legislate.

This subcommittee, in particular, is charged with the responsibility of seeking out and gathering information wherever we can. This information is of crucial importance to the activities of this subcommittee.

We have reason to believe that the large trade name drug companies have been regularly making unfair profits, charging 5,000 percent markup on medicines which people in need of medicine have to pay, simply because it is a brand name.

We have reason to believe that there is no reason they should have that kind of markup.

We have asked for the information. It has been denied to us.

Mr. Lent. You have gone beyond our time.

Mr. Moss. The Chair shows 1¾ minutes so far. Therefore, he can continue for a full 2 minutes.

Mr. Gore. I appreciate the courtesy of both gentlemen.

I would say to those of my colleagues who might be undecided still, that every alternative course of action which has been recommended has serious defects. This course of action has not been taken lightly at all. We have been engaged in negotiations for 5 long weeks.

This subcommittee and the chairman of this subcommittee have distinguished records of serving the public interest.

Mr. Moss. The gentleman's time has passed.

The question occurs on ordering the previous question.

As many as are in favor will indicate by saying aye.

[Chorus of ayes.]

Mr. Moss. Those opposed?

[No response.]

Mr. Moss. The previous question is ordered.

The vote occurs on the motion that the committee do now reconsider the vote whereby the resolution of contempt was tabled.

Mr. Collins. I ask for a rollcall.

Mr. Moss. The clerk will call the roll.
The CLERK. Mr. Santini?
Mr. SANTINI. Aye.
The CLERK. Mr. Luken?
[No response.]
The CLERK. Mr. Walgren?
[No response.]
The CLERK. Mr. Gore?
Mr. GORE. Aye.
The CLERK. Mr Carney?
[No response.]
The CLERK. Mr. Waxman?
Mr. WAXMAN. Aye.
The CLERK. Mr. Sharp?
[No response.]
The CLERK. Mr. Moffett?
Mr. MOFFETT. Aye.
The CLERK. Mr. Maguire?
Mr. MAGUIRE. Aye.
The CLERK. Mr. Krueger?
[No response.]
The CLERK. Mr. Collins?
Mr. COLLINS. No.
The CLERK. Mr. Lent?
Mr. LENT. No.
The CLERK. Mr. Rinaldo?
Mr. RINALDO. No.
The CLERK. Mr. Stockman?
[No response.]
The CLERK. Mr. Marks?
Mr. MARKS. No.
The CLERK. Mr. Moss?
Mr. Moss. Aye.
The CLERK. Mr. Luken?
[No response.]
The CLERK. Mr. Walgren?
Mr. WALGREN. Aye.
The CLERK. Mr. Chairman, I have a proxy from Mr. Devine for Mr. Collins.
Mr. COLLINS. Mr. Devine votes no, by proxy.
The CLERK. Mr. Chairman, I have a proxy from Mr. Stockman for Mr. Collins.
Mr. COLLINS. Mr. Stockman votes no, by proxy.
The CLERK. Mr. Chairman, I have a proxy from Mr. Carney for you.
Mr. Moss. Mr. Carney votes aye, by proxy.
The CLERK. Mr. Chairman, I have a proxy from Mr. Staggers for you.
Mr. Moss. Mr. Staggers votes aye, by proxy.
The CLERK. Mr. Chairman, I have a proxy from Mr. Sharp for you to vote.
Mr. Moss. Mr. Sharp votes aye, by proxy.
The CLERK. Mr. Chairman, I have a proxy from Mr. Krueger for Mr. Walgren to vote.

Mr. WALGREN. Mr. Krueger would vote no, by proxy.

The CLERK. Mr. Luken?

Mr. LUKEN. Aye.

The CLERK. Mr. Chairman, the vote is 11 ayes and 7 nays.

Mr. Moss. And the motion to reconsider carries.

The question then would occur on the resolution offered by the gentleman from Tennessee, Mr. Gore, that the committee do now recommend to the full Committee on Interstate and Foreign Commerce that we find the Secretary of HEW in contempt of the House.

Mr. WALGREN. Parliamentary inquiry, Mr. Chairman.

I am looking for the opportunity to offer, or see to it that the committee is offered, in some way an ability to schedule this vote and grapple this issue 2 weeks hence.

I would like to know whether there is any particular time when such a motion can be in order.

Mr. Moss. The Chair would point out that technically the motion to table lies before the members because that is the motion upon which reconsideration has been ordered.

Is there further discussion?

Mr. WAXMAN. The gentleman addressed a parliamentary inquiry, whether there would be some process by which the issue of the contempt resolution could be before this committee for a vote—not at this meeting but at a meeting when we return from the Labor Day recess.

I assume a motion to table, if successful, does not give this committee an opportunity to reconsider it unless it were placed on the calendar again.

I would rather keep the issue alive. I gather if there were a motion to postpone the vote to a time certain, that that would be in order parliamentarily.

Mr. Moss. That is the same as a motion to table, is it not? You have to wait until we have disposed of the motion to table.

Mr. WAXMAN. Parliamentary point.

The motion now before us is a motion to table.

Mr. Moss. That is correct.

Mr. WAXMAN. If that were defeated, then another motion would be in order at that time to defer the issue to a time certain?

Mr. Moss. We must first vote on the underlying motion, the motion to table.

Mr. MARKS. Parliamentary inquiry.

Under what we are now considering, would it be possible for Mr. Lent at this point to amend his motion to include a time certain in the future?

Mr. Moss. It would be a substitute motion. I believe we must vote on the question of whether or not the reconsideration occurs. Reconsideration has been ordered.

We move then to reconsider the vote, inasmuch as that was the motion, whereby the motion to table was carried.

Once that is disposed of, then the slate is clean and other amendments or proposals might be offered, but not prior to the vote on the motion to table.

Mr. MARKS. Parliamentary inquiry, if you can call it that at this point.

I know there is some desire to perhaps delay this matter for a reasonable period of time. I understand and appreciate how strongly the chairman feels.

However, under the circumstances at this time, would the chairman consider whatever procedural steps have to be taken to postpone a vote on the contempt citation until we return?

Mr. Moss. I do not think any member has ever had his rights compromised as a result of any action by the Chair.

Mr. MARKS. I am sure of that.

Mr. Moss. The question occurs on the motion to lay on the table.

As many as are in favor of laying the resolution citing the Secretary for contempt by this subcommittee shall indicate by saying aye; those opposed will say nay.

The Clerk will call the roll.

The CLERK. Mr. Santini?

Mr. SANTINI. No.

The CLERK. Mr. Luken?

Mr. LUKEN. No.

The CLERK. Mr. Walgren?

Mr. WALGREN. No.

The CLERK. Mr. Gore?

Mr. GORE. No.

The CLERK. Mr. Carney?

[No response.]

The CLERK. Mr. Waxman?

Mr. WAXMAN. No.

The CLERK. Mr. Sharp?

[No response.]

The CLERK. Mr. Moffett?

Mr. MOFFETT. No.

The CLERK. Mr. Maguire?

Mr. MAGUIRE. No.

The CLERK. Mr. Krueger?

[No response.]

The CLERK. Mr. Collins?

Mr. COLLINS. Aye.

The CLERK. Mr. Lent?

Mr. LENT. Aye.

The CLERK. Mr. Rinaldo?

Mr. RINALDO. Aye.

The CLERK. Mr. Stockman?

[No response.]

The CLERK. Mr. Marks?

Mr. MARKS. Aye.

The CLERK. Mr. Moss.

Mr. Moss. No.

The CLERK. Mr. Chairman, I have a proxy of Mr. Devine for Mr. Collins.

Mr. COLLINS. He votes aye, by proxy.

The CLERK. I have a proxy from Mr. Stockman for Mr. Collins.

Mr. COLLINS. He votes aye, by proxy.

The CLERK. I have a proxy from Mr. Carney for Mr. Moss.

Mr. Moss. He votes no.

The CLERK. I have a proxy from Mr. Staggers for Chairman Moss.
Mr. Moss. Mr. Staggers votes no.
The CLERK. I have a proxy from Mr. Sharp for Mr. Moss.
Mr. Moss. Mr. Sharp votes no.
The CLERK. I have a proxy from Mr. Krueger for Mr. Walgren.
Mr. WALGREN. Mr. Krueger votes aye.
The CLERK. Mr. Chairman, the vote is 7 ayes and 11 nays.
Mr. Moss. The motion to lay on the table is not agreed to.
The question now before the committee is the motion offered by the gentleman from Tennessee, Mr. Gore.
I will ask the clerk to re-report that motion so that it is clearly available to every member.
The CLERK. Resolved that:
(1) The subcommittee finds Joseph A. Califano, Jr., in contempt for failure to comply with subpena No. 95–2–75 issued by the subcommittee on August 4, 1978; and
(2) The facts of this failure be reported by the chairman of the Subcommittee on Oversight and Investigations to the Committee on Interstate and Foreign Commerce for such action as that committee deems appropriate.
Mr. RINALDO. Parliamentary inquiry.
Would a motion be in order at this point to postpone the vote on the resolution until a time certain?
Mr. Moss. Any motion which under the rules is in order is now in order.
Mr. RINALDO. I would then make a motion at this point that the vote on the resolution be postponed until Wednesday, September 6.
May I speak on the motion?
Mr. Moss. The gentleman is recognized for 5 minutes.
Mr. MOFFETT. Parliamentary inquiry.
Is the motion of the gentleman in fact in order? If so, how does it become in order, given the fact that the resolution offered by the gentleman from Tennessee is now before us?
Mr. Moss. The resolution is before us and, as all legislative vehicles, it is subject to amendment.
Mr. MOFFETT. It is in the form of an amendment, then.
Mr. Moss. Both as to the form of the motion itself or to a device for disposal of the motion. This, in effect, is a motion to postpone to a time certain consideration of the motion.
The gentleman from New Jersey is recognized for 5 minutes.
Mr. RINALDO. I will not need the entire 5 minutes, Mr. Chairman.
I want to state I agree completely with you regarding the seriousness of the matter. I agree that the prerogatives of the Congress are at stake. I agree we do have a right to the information and that we need the information.
I would hope during the intervening period of time, the short period of time, that perhaps the Secretary will have an opportunity to discuss the matter further with the Attorney General and others in the Department of Justice. Perhaps there will be a solution offered. Perhaps the Secretary will decide to comply, realizing the seriousness of the matter and the fact that the votes are here for the contempt citation, to comply with the request of the committee.

If not, I will state for the record, Mr. Chairman, I will change my vote, which was previously against citation, in favor of a contempt citation when we reconvene and a meeting is held.

Mr. WAXMAN. I would like to suggest, and perhaps you can ask unanimous consent, that the amendment be amended to state that the date of September 6 or such other time procedurally or as soon thereafter as the chairman can reconvene the committee.

Mr. RINALDO. I will accept that. I will ask unanimous consent that the amendment be amended to read September 6 or such time thereafter as the chairman may call the meeting.

I yield back the balance of my time.

Mr. Moss. Is there further discussion?

Mr. WAXMAN. Some of our colleagues, in an effort to be very fair, feel that the Secretary ought to have additional time within which to consider whether he would go against the direction of a Congress to turn over the information subpenaed, and also, perhaps for the purpose of some negotiation which might be successful in averting the drastic action contemplated.

I quite frankly think that we have had enough time. We subpenaed the information. We have had negotiations. The Secretary understands the legal implications of this, and he is refusing, stonewalling if you will, to give us the information that Congress is entitled to receive.

However, I want to point out that I will vote against this motion, because I think we are ready at the present time to proceed to a vote of contempt.

However, I understand and respect the judgment of some of my colleagues who want to have more time to take care of that problem; and at the end of that time, I hope at that point we will see, if we have not resolved it, and perhaps we will have resolved it and I would be delighted, but at that point they will join the rest of us and realize that the issue then becomes the question of the right of Congress to know and the assertion of our powers under the Constitution.

Mr. Moss. Is there further discussion?

Mr. SANTINI. I share the basic sentiments of the gentleman from California. I would lend only the emphasis of my negative expectations about the delay of 3 weeks. It will only produce a delay of 3 weeks, and we will be setting down and examining the basic propositions 3 or 4 weeks from now, which we could have resolved and reconciled today.

I am persuaded by past experience that inaction never produces action. This, in essence, is the solution being offered to us today.

I share the hopes and aspirations of my good friends on the minority that this dormant period of time will evolve a change in posture, but I have considerable pessimism.

Mr. Moss. Is there further discussion?

[No response.]

Mr. Moss. If the Chair may be permitted, I will say to you that we have taken 5 long and difficult weeks in arriving at nothing.

We are now being asked to postpone for at least 3 more weeks, the probability of work facing us perhaps, allowing no more than 4 or 5 additional weeks before we take any kind of action moving us closer

to a resolution of the present disagreement between the Department of Justice, the Department of HEW, and this committee.

I am convinced that if we move today, as I am confident we should, to adopt the resolution offered by the gentelman from Tennessee, that we will be moving toward the kind of situation that might bring about a resolution short of the ultimate confrontation before the full committee and on the floor of the House. That is the reason I have recommended this course of action to the committee.

I point out that the Chair has caused the subpena to be served quite a long time after this committee authorized it in an effort still to try to get an agreement.

In my judgment, no agreement is possible.

I mentioned my view earlier with regard to the present Attorney General and his attitude toward the rights and needs of the Congress. I am convinced that I stated the situation very correctly, and that we have no hope of resolving the matter with the Attorney General.

I might point out to this subcommittee that I had to go through months of negotiating on behalf of this subcommittee after the court of appeals gave us the right of access to material under the *A.T. & T.* case and encountered every kind of nitpicking roadblock you can conceive from the Department of Justice, notwithstanding the clear language of the court of appeals.

I know what they understand over there, and the kind of indecision here today is not the kind of thing they either respect or understand.

Mr. GORE. I thank the Chair for yielding. I will be very brief.

I want simply to note the fact that a vote by this subcommittee is not in and of itself a contempt citation. It is a recommendation to the full committee that it recommend to the full Congress a contempt citation.

Delay has been suggested. Delay is inherent in the course of action which I proposed. We recommend to the full committee a citation of contempt based upon the fruitless and long effort we have been engaged in.

The full committee will not meet to consider this contempt citation until after the period of time previously suggested as a delay by this subcommittee.

After the full committee acts, assuming it does, then there is a further delay before the full Congress acts.

During those two periods of delay, both of them hypothetical, the Secretary will have an opportunity to negotiate with the chairman of this subcommittee and with the staff of the subcommittee in an effort to come to some mutually acceptable resolution of this conflict.

If we, on the other hand, delay our recommendation to the full committee, the period is protracted. We take a step backward.

The Secretary and the Department then have no incentive whatsoever to engage in further discussion.

I thank the chairman for yielding.

Mr. COLLINS. Mr. Chairman, I move the previous question on the Rinaldo amendment.

Mr. Moss. Is there objection to putting the previous question?

[No response]

Mr. Moss. If not, then the question occurs on the motion of the gentleman from New Jersey that this matter be postponed for action until the 6th of September or such date thereafter as may reasonably be

available for the scheduling of further business of the subcommittee.
Those in favor of the amendment will indicate by saying aye.
[Chorus of ayes.]
Mr. Moss. Those opposed will indicate by saying no.
[Chorus of noes.]
Mr. Moss. In the opinion of the Chair, the noes have it.
Mr. RINALDO. I ask for a rollcall.
Mr. Moss. A rollcall is demanded, and the Clerk will call the roll.
The CLERK. Mr. Santini?
Mr. SANTINI. No.
The CLERK. Mr. Luken?
[No response.]
The CLERK. Mr. Walgren?
Mr. WALGREN. Aye.
The CLERK. Mr. Gore?
Mr. GORE. No.
The CLERK. Mr. Garney?
[No response.]
The CLERK. Mr. Waxman?
Mr. WAXMAN. No.
The CLERK. Mr. Sharp?
[No response.]
The CLERK. Mr. Moffett?
Mr. MOFFETT. No.
The CLERK. Mr. Maguire?
Mr. MAGUIRE. No.
The CLERK. Mr. Krueger?
[No response.]
The CLERK. Mr. Collins?
Mr. COLLINS. Aye.
The CLERK. Mr. Lent?
Mr. LENT. Aye.
The CLERK. Mr. Rinaldo?
Mr. RINALDO. Aye.
The CLERK. Mr. Stockman?
[No response.]
The CLERK. Mr. Marks?
Mr. MARKS. Aye.
The CLERK. Mr. Moss?
Mr. Moss. No.
The CLERK. Mr. Chairman, I have a proxy from Mr. Devine for Mr. Collins.
Mr. COLLINS. Mr. Devine votes aye, by proxy.
The CLERK. Mr. Chairman, I have a proxy from Mr. Stockman for Mr. Collins.
Mr. COLLINS. Mr. Stockman votes aye.
The CLERK. I have a proxy from Mr. Carney for Mr. Moss.
Mr. Moss. Mr. Carney votes no.
The CLERK. I have a proxy from Mr. Staggers for Chairman Moss.
Mr. Moss. Mr. Staggers votes no.
The CLERK. I have a proxy from Mr. Sharp for Chairman Moss.
Mr. Moss. Mr. Sharp votes no.

The CLERK. I have a proxy from Mr. Krueger for Mr. Walgren.
Mr. WALGREN. Mr. Krueger votes aye, by proxy.
The CLERK. I have a proxy from Mr. Luken for Mr. Walgren.
Mr. WALGREN. Mr. Luken votes aye, by proxy.
The CLERK. Mr. Chairman, the vote is nine ayes and nine nays.
Mr. Moss. And the motion is not agreed to.
Mr. GORE. I move the previous question on my resolution. We have talked long enough.
Mr. Moss. Is there objection to placing the previous question?
If not, the question occurs on the resolution offered by the gentleman from Tennessee, Mr. Gore, calling for the citation of contempt for the Secretary.
The Chair, anticipating the desires of the members, directs the clerk to call the roll.
The CLERK. Mr. Santini?
Mr. SANTINI. Aye.
The CLERK. Mr. Luken?
[No response.]
The CLERK. Mr. Walgren?
Mr. WALGREN. No.
The CLERK. Mr. Gore?
Mr. GORE. Aye.
The CLERK. Mr. Carney?
[No response.]
The CLERK. Mr. Waxman?
Mr. WAXMAN. Aye.
The CLERK. Mr. Sharp?
[No response.]
The CLERK. Mr. Moffett?
Mr. MOFFETT. Aye.
The CLERK. Mr. Maguire?
Mr. MAGUIRE. Aye.
The CLERK. Mr. Krueger?
[No response.]
The CLERK. Mr. Collins?
Mr. COLLINS. No.
The CLERK. Mr. Lent?
Mr. LENT. No.
The CLERK. Mr. Rinaldo?
Mr. RINALDO. No.
The CLERK. Mr. Stockman?
[No response.]
The CLERK. Mr. Marks?
Mr. MARKS. No.
The CLERK. Mr. Moss?
Mr. Moss. Aye.
The CLERK. Mr. Chairman, I have a proxy from Mr. Devine for Mr. Collins.
Mr. COLLINS. He votes no.
The CLERK. I have a proxy from Mr. Stockman for Mr. Collins.
Mr. COLLINS. He votes no.
The CLERK. I have a proxy from Mr. Carney for Chairman Moss.
Mr. Moss. He votes aye.

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The CLERK. I have a proxy from Mr. Staggers for Chairman Moss.
Mr. Moss. He votes aye.
The CLERK. I have a proxy from Mr. Sharp for Chairman Moss.
[No response.]
The CLERK. I have a proxy from Mr. Krueger for Mr. Walgren.
Mr. WALGREN. Mr. Krueger votes no.
The CLERK. I have a proxy from Mr. Sharp for Chairman Moss.
Mr. Moss. He votes aye.
Mr. LENT. Parliamentary inquiry, Mr. Chairman.
Was Mr. Luken recorded?
Mr. Moss. I do not know. I had to step out of the room briefly.
The CLERK. I had a proxy for Mr. Luken previously, but it was withdrawn when the other one was given.
Mr. WALGREN. I was under the understanding that I had a proxy from Mr. Luken. I do not know whether he withdrew it from me.
Mr. Luken had expressed a desire to be voted no.
Mr. SANTINI. Do we have a proxy from Mr. Luken to Mr. Walgren?
The CLERK. Mr. Luken previously gave a proxy to Mr. Walgren. Then, when Mr. Luken came into the room, it was withdrawn.
I now have a proxy for Mr. Luken but only with regard to the resolution to postpone until September 6.
Mr. WAXMAN. We are in the middle of a vote and perhaps Mr. Luken can get here to vote.
Mr. Moss. Let me see the proxy.
[Clerk hands proxy to Chairman Moss.]
Mr. Moss. Is Mr. Luken coming here?
[No response.]
Mr. Moss. The Chair will ask unanimous consent that the committee hold the roll for 2 additional minutes in order to permit the gentleman from Ohio to vote.
Is there objection?
[No response.]
Mr. Moss. Hearing none——
Mr. MARKS. Reserving my right to object, the chairman has limited that to only 2 minutes, as I understand it.
I note Mr. Luken's administrative aide is on the telephone. He might not be able to make it in 2 minutes. It might take 3, 4, or perhaps even 5 minutes.
Would the chairman give a more reasonable period of time?
Mr. Moss. The chairman believes that any wait, to be very candid, is a very reasonable period of time, in view of the fact that the rules contemplate presence.
Mr. COLLINS. I agree with the chairman.
Mr. Moss. The Chair has a lot of business to conduct. I have been here since 9:30, as has the gentleman, and has the gentleman from Texas and most of the other members.
Mr. MOFFETT. Is the unanimous consent request before us?
Mr. Moss. Yes.
Mr. MOFFETT. Reserving the right to object.
Mr. Moss. Go ahead.
Mr. MOFFETT. I think your remarks are absolutely on target. Most of us have been sitting here listening to the debate, grappling with the problem.

Obviously, there is a bit of confusion, but both the majority and the minority have seen the proxy, which is deficient in terms of its being cast in any way on the contempt resolution itself.

I object.

Mr. Moss. The clerk will announce the vote.

Mr. MARKS. Parliamentary inquiry.

Mr. Moss. The Chair has heard an objection. We are in the middle of a rollcall, and we have no alternative but to have the Clerk announce the roll.

Mr. MARKS. Might I make a parliamentary inquiry?

Mr. Moss. Yes.

Mr. MARKS. My inquiry is that I note Mr. Luken's staff member is there, perhaps getting the information we ought to have.

Mr. Moss. I cannot take the verbal statement. A member may not vote by voice vote by proxy.

The Clerk will announce the vote.

Mr. LENT. I make a point of order.

Mr. Moss. The Clerk will announce the vote. We are in the middle of a rollcall. The Clerk will announce the rollcall.

The CLERK. Nine ayes and eight nays.

Mr. Moss. Accordingly, the motion carries.

Now if the gentleman wants to make a point of order.

Mr. LENT. My point of order, which might be academic now, is that the House is operating under the 5-minute rule.

Mr. Moss. The gentleman's motion is in order.

Mr. LENT. I will withdraw it at this point, inasmuch as I was not recognized before the vote was announced.

[The balance of the meeting did not relate to Secretary Califano and therefore is not printed in this document.]

[Whereupon at 1:32 p.m., the subcommittee adjourned.]

APPENDIX

95-2-75

ORIGINAL

BY AUTHORITY OF THE HOUSE OF REPRESENTATIVES OF THE CONGRESS OF THE UNITED STATES OF AMERICA

To Elliot Segal and/or Susan Leal and/or Allegra McManus

You are hereby commanded to summon Honorable Joseph Califano, Secretary of Health, Education, and Welfare

to be and appear before the Subcommittee on Oversight and Investigations (under the authority of Rules X and XI of the Rules of the House of Representatives, 95th Congress) of the Interstate and Foreign Commerce Committee of the House of Representatives of the United States, of which the Hon. John E. Moss is chairman, and to bring with him the documents described in the attachment to this subpoena (personal appearance is not required if the described materials are produced at the Subcommittee offices by 5:00 p.m., Friday, August 11, 1978)

in their chamber in the city of Washington, on Wednesday, August 16, 1978 in Room 2323 Rayburn House Office Building, at the hour of 9:30 a.m.

then and there to testify touching matters of inquiry committed to said Committee; and he is not to depart without leave of said Committee.

Herein fail not, and make return of this summons.

Witness my hand and the seal of the House of Representatives of the United States, at the city of Washington, this 4th day of August, 19 78

Harley O. Staggers
Chairman.

Attest: Edmund L. Henshaw Jr.
Clerk.

ATTACHMENT TO SUBPOENA NO. 95-2-75

Copies of any and all Abbreviated New Drug Applications and Form 6, including all amendments, supplements, amendments to supplements and/or correspondence that are filed in support of or addition to the Abbreviated New Drug Applications and Form 6 filed by E. R. Squibb and Sons, Inc., Syntex Labs, Bristol Laboratories, Pfizer Laboratories, Parke, Davis and Company, Merck, Sharp and Dohme, Cord Laboratories, John D. Copanis Company, Mylan Pharmaceutical, K-V Laboratories, Barr Laboratories, Biocraft Laboratories, and McKesson Laboratories since January 1965.

ORIGINAL

Subpena for ....

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before the Committee on the ....

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Served upon Frank [illegible]
General Counsel, HEW
Aug 10, 1978 for
Joseph A. Califano Jr.
Sec. of Dept of Health
Education and Welfare
Aug 10, 1978
Served by [illegible] on Aug 10, 1978
for the .... House of Representatives
11:21 a.m.

U.S. GOVERNMENT PRINTING OFFICE 71-600-1

NINETY-FIFTH CONGRESS

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SAMUEL L. DEVINE, OHIO (EX OFFICIO)

CONGRESS OF THE UNITED STATES
HOUSE OF REPRESENTATIVES
SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS
OF THE
COMMITTEE ON INTERSTATE AND FOREIGN COMMERCE
WASHINGTON, D.C. 20515

ROOM 2323
RAYBURN HOUSE OFFICE BUILDING
PHONE (202) 225-4441

JAMES L. NELLIGAN
OPERATIONS DIRECTOR

JOHN MC ELROY ATKISSON
COUNSEL TO THE SUBCOMMITTEE

TASK FORCE DIRECTORS
LOWELL DODGE—GOVERNMENT
JOHN R. GALLOWAY—ENERGY
ELLIOT A. SEGAL—HEALTH

J. THOMAS GREENE
COUNSEL TO THE CHAIRMAN

BERNARD J. WUNDER
MINORITY COUNSEL

July 11, 1978

HAND DELIVERED

Honorable Joseph A. Califano, Jr.
Secretary of Health, Education
and Welfare
Washington, D. C. 20201

Dear Mr. Secretary:

The Subcommittee on Oversight and Investigations, under the authority of Rules X and XI of the United States House of Representatives, is continuing its investigation into the regulation of drugs.

We request that you assist us by providing the following materials:

1. All documents, correspondence and inter-office memoranda relating to the practice of manufacturing prescription drugs in facilities that are leased by the manufacturer, or in facilities that are shared with other drug manufacturers, practices sometimes referred to as "man in the plant."

2. All Establishment Inspection Reports (EIR) and all documents gathered pursuant to inspections of facilities that have been or are being leased by drug manufacturers or have been or are being shared by more than one drug manufacturer. These EIR or inspection records should include, but not be limited to, batch records, manufacturers procedures and yield accountability figures.

3. Please list all manufacturers of prescription drugs that manufacture drugs in leased facilities or in facilities that they share with other manufacturers.

4. For each of the manufacturer(s) that comes within category 3, please list the drug(s) that are manufactured in leased or shared facilities and the location of those facilities.

5. Information requested in categories 1 through 4 should extend to all information gathered since 1972.

The Subcommittee would appreciate receiving these materials no later than July 18, 1978. If you have any questions, please contact Ms. Susan Leal or Mr. Elliot Segal of the Subcommittee staff at 225-4441.

Thank you for your assistance and cooperation.

Sincerely,

JOHN E. MOSS
Chairman
Subcommittee on
Oversight and Investigations

JEM:sla

THE SECRETARY OF HEALTH, EDUCATION, AND WELFARE
WASHINGTON, D.C. 20201

JUL 31 1978

The Honorable John E. Moss
Chairman, Subcommittee on Oversight
and Investigations
Committee on Interstate and
Foreign Commerce
House of Representatives
Washington, D.C. 20515

Dear John:

Thank you for your letter of July 11 concerning your investigation of the regulation of drugs. The Food and Drug Administration (FDA) has furnished materials in response to item 1 of your letter as follows:

Tab 1--Prepared FDA testimony and letter of invitation for November 14, 1977, hearing before the Subcommittee on Monopoly of the Senate Select Committee on Small Business.

There is a section on page 6 "General Current Labeling Practices--Existing Problems" which includes a discussion of the so-called "man-in-the-plant" mechanism.

Tab 2--Documents, correspondence and memoranda relating to "man-in-the-plant."

The FDA has informed me that because correspondence is filed primarily by company and not by subject in drug listing and other files, they undoubtedly did not locate all correspondence on the subject of the man-in-the-plant mechanism. If upon additional search, other examples are found, however, they will forward them to you.

I have enclosed a copy of Commissioner Kennedy's memorandum to me on the subject of your request of July 11 (Tab 3). As you may note in the last paragraph, your staff has agreed to meet the FDA to work out a plan to obtain the type of information needed in the shortest possible time.

Sincerely,

Joseph A. Califano, Jr.

Enclosures

CONGRESS OF THE UNITED STATES
HOUSE OF REPRESENTATIVES
SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS
OF THE
COMMITTEE ON INTERSTATE AND FOREIGN COMMERCE
WASHINGTON, D.C. 20515

July 21, 1978

HAND DELIVERED

Honorable Joseph A. Califano, Jr.
Secretary of Health, Education
and Welfare
Washington, D. C. 20201

Dear Mr. Secretary:

The Subcommittee on Oversight and Investigations, under the authority of Rules X and XI of the United States House of Representatives, is continuing its investigation into the regulation of drugs.

To further this investigation, we request that you provide the Subcommittee staff with access to those documents outlined in their meeting with Commissioner Kennedy on July 20, 1978. Specifically, we request access to all New Drug Applications (NDAs), Abbreviated New Drug Applications (ANDAs), Forms 5 and 6 that have been filed by drug manufacturers and/or distributors with the Food and Drug Administration (FDA). Access shall include reviewing and copying of documents.

In a brief conversation between Subcommittee staff and Richard Cooper, General Counsel to the FDA, Mr. Cooper indicated that there may be some difficulty in giving the Subcommittee access to these documents because of Section 301(j) of the Food, Drug, and Cosmetic Act. As we discussed, in the context of the Ashland litigation, Congress would not, other than by a specific and very explicit statutory prohibition, limit its rights to information necessary to carry out its responsibilities under Article I of the Constitution.

A similar provision of law was at the heart of the Subcommittee's disagreement with former Secretary of Commerce, Rogers C. B. Morton. As a consequence, I am sending you records of the hearings concerning Mr. Morton. I would direct your particular attention to the testimony of Professors Raoul Berger, Norman Dorsen, and Philip B. Kurland beginning at pages 49, 86, and 101 respectively, con-

cerning a provision similar to Section 301(j) of the Food, Drug, and Cosmetic Act.

I look forward to a response to the Subcommittee's request by 5:00 p.m., Monday, July 24, 1978. I would appreciate receiving your full cooperation in this matter.

Sincerely,

JOHN E. MOSS
Chairman
Subcommittee on
Oversight and Investigations

JEM:sla

Enclosures

CONGRESS OF THE UNITED STATES
HOUSE OF REPRESENTATIVES
SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS
OF THE
COMMITTEE ON INTERSTATE AND FOREIGN COMMERCE
WASHINGTON, D.C. 20515

August 14, 1978

Honorable Joseph Califano
The Secretary
Department of Health, Education,
and Welfare
Washington, D. C. 20201

Dear Mr. Secretary:

As you know this Subcommittee's subpoena No. 95-2-75 served upon HEW General Counsel F. Peter Libassi on August 10, 1978, is directed to you personally. That subpoena indicated that your own personal appearance before the Subcommittee would be unnecessary, should you be inclined to deliver the documents we require by 5:00 p.m. Friday, August 11. That deadline, regrettably, has passed without any indication of compliance with the Subcommittee's requests on the part of HEW.

Consequently, by the terms of the subpoena, you are required to appear personally before the Subcommittee this Wednesday, August 16, at 9:30 a.m. in Room 2357 of the Rayburn House Office Building.

Lest there be any doubt about the Subcommittee's position in this matter, please be advised that your own personal appearance is required, notwithstanding the eminence and good intentions of some of your assistants. Your failure to appear will be viewed by this Chairman as a separate and additional act of contempt.

I look forward to seeing you Wednesday morning.

Sincerely,

JOHN E. MOSS
Chairman
Subcommittee on
Oversight and Investigations

JEM:jaj

cc: F. Peter Libassi, Esquire